From Lab Benches to Primary Care Trenches:
Recognizing, Mitigating, and Preventing Diagnostic Errors

CDC CLIAC Conference 11/7/18

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Academic Improvement Collaborative

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BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S
Department of Medicine

CENTER FOR PRIMARY CARE
HARVARD MEDICAL SCHOOL

HARVARD MEDICAL SCHOOL
Global and Continuing Education

Financial Conflicts/Disclosures

- **None relevant to talk**
- **Commercial**
  - None related (Medaware software evaluation)
- **Other/Grant Funding**
  - **CRICO Malpractice Grants–Diagnostic Errors/Pitfalls**
  - **Gordon & Betty Moore Foundation- Diagnostic Error Projects**
  - **SIDM/PCORI Research Mentor honorarium**
  - AHRQ –HIT Safety Grant –Drug Indications
  - Gold Foundation- Boundaries Issues

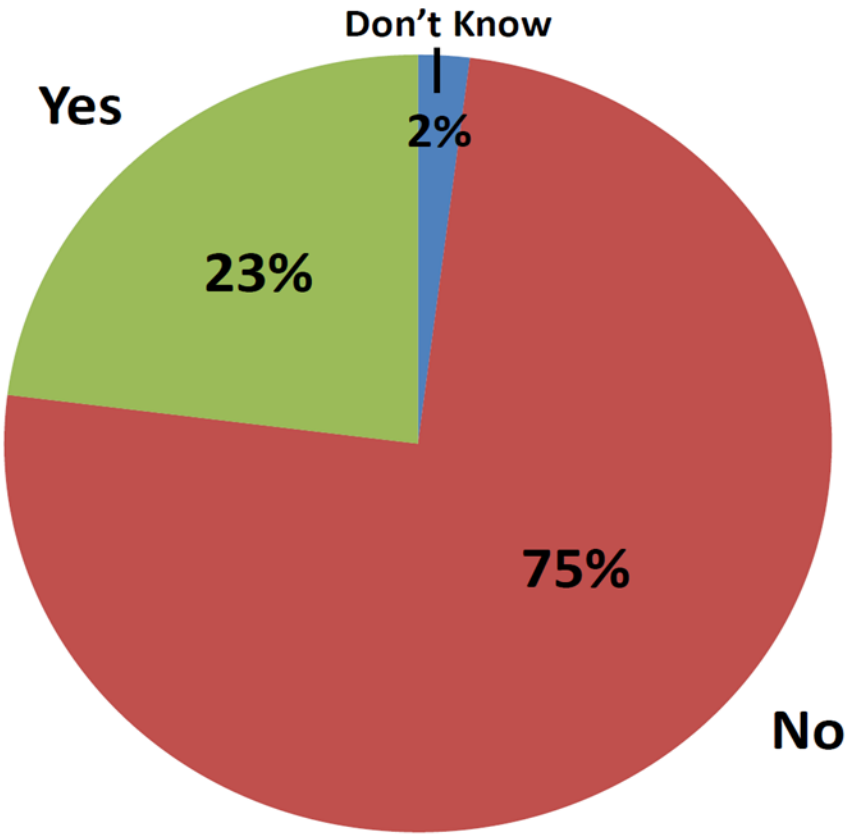
Outline-Trenches to Benches

- **Importance/Relevance Diagnostic Error**
- **Conceptual models – Dx as a System**
  - Venn diagram – what is a diagnosis error
- **Role of lab in diagnostic error**
  - Prominence
  - Rethinking PreAnalytic/Analytic/PostAnalytic Model
- **Ways forward**
  - Indications-based ordering
  - PROMISES, Pitfalls, PRIDE Projects
  - Health IT; Linking Lab and Drug data
  - Forging a culture of diagnostic safety

MA Residents Involved in a Medical Error Situation

BETSY LEHMAN CENTER for Patient Safety and Medical Error

% saying personally involved in a situation where a preventable medical error was made in their own care or in the care of someone close to them



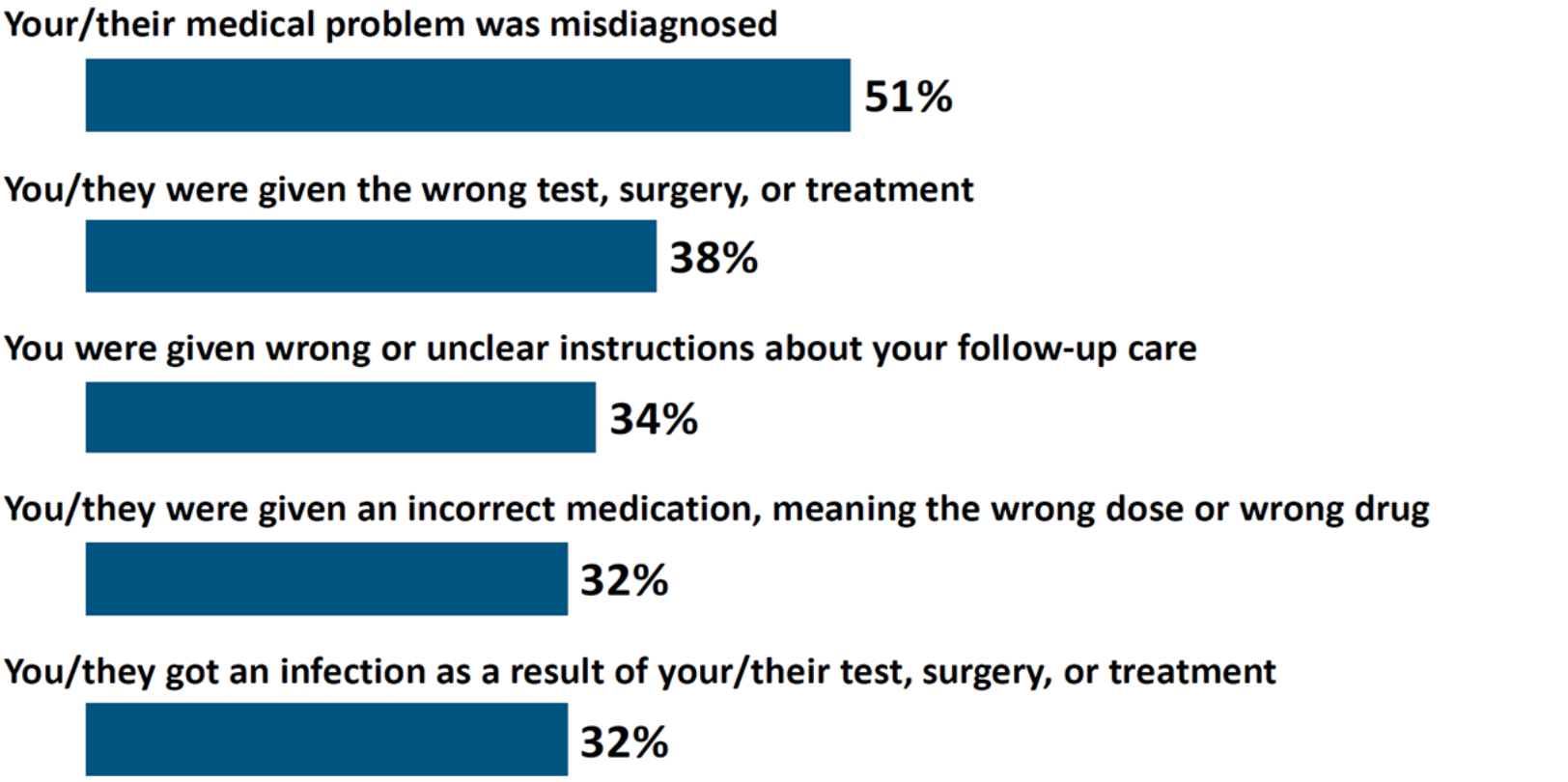
Harvard School of Public Health / Betsy Lehman Center for Patient Safety and Medical Error Reduction / Health Policy Commission
The Public's Views on Medical Error in Massachusetts, September 2 – 28, 2014.

Most Common Types of Medical Error Experienced by MA Residents

BETSY LEHMAN CENTER
for Patient Safety and Medical Error R

% saying…

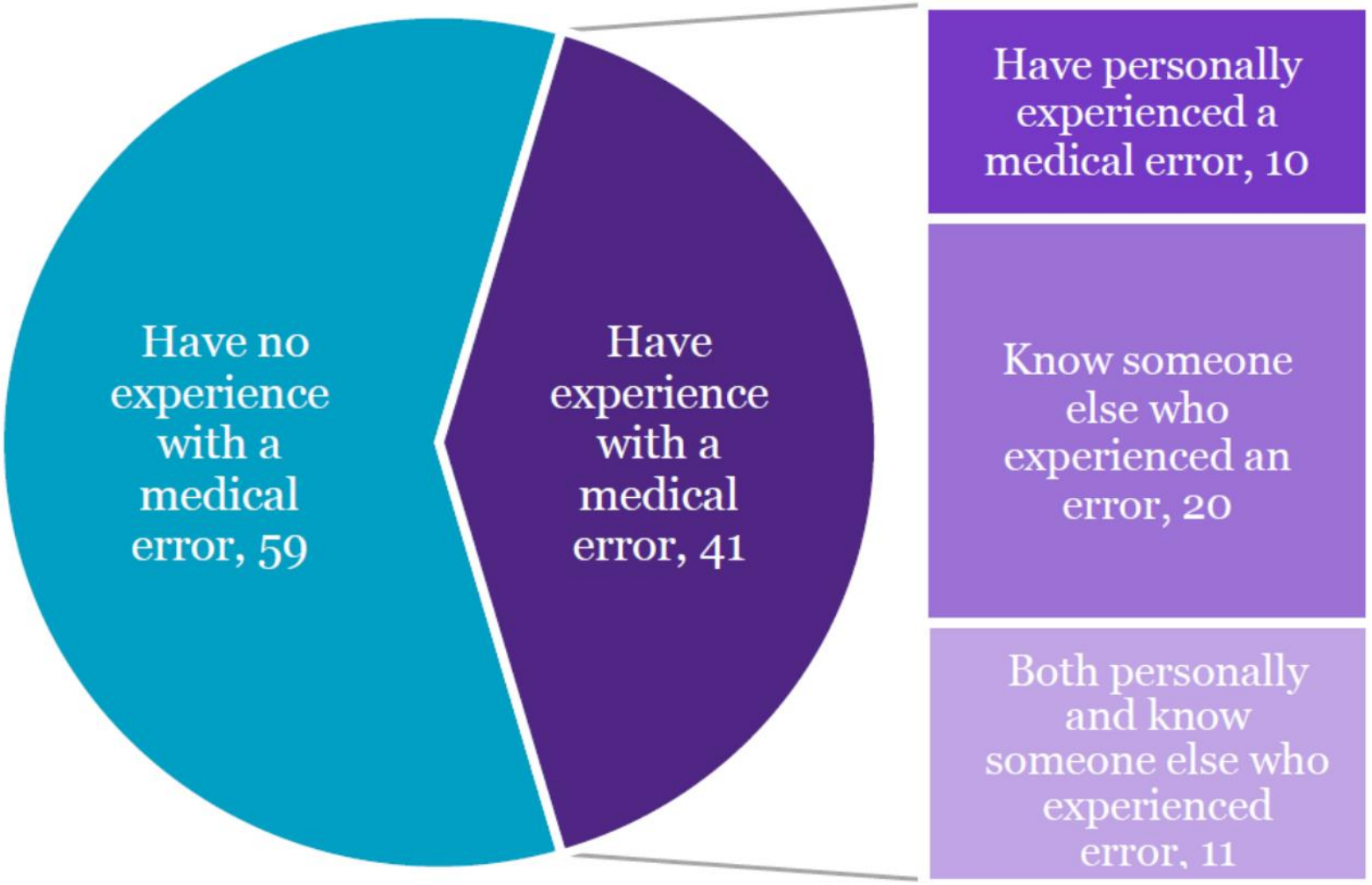
(Among the 23% who said they or a person close to them experienced a medical error)



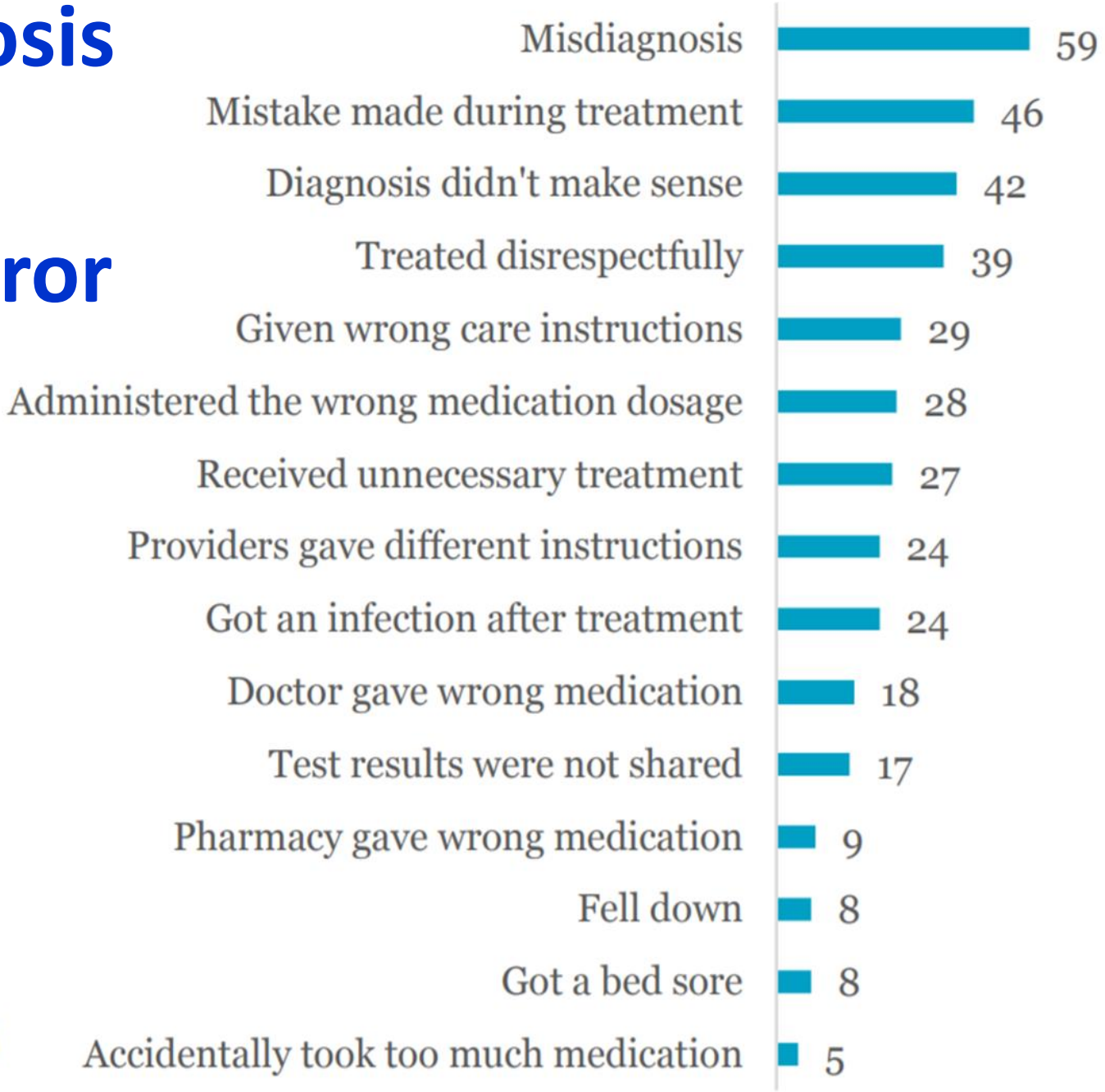
Harvard School of Public Health / Betsy Lehman Center for Patient Safety and Medical Error Reduction / Health Policy Commission
The Public's Views on Medical Error in Massachusetts, September 2 – 28, 2014.

21% Experienced medical error

IHI/NPSF
2017 Survey



Misdiagnosis Leading Type of Error

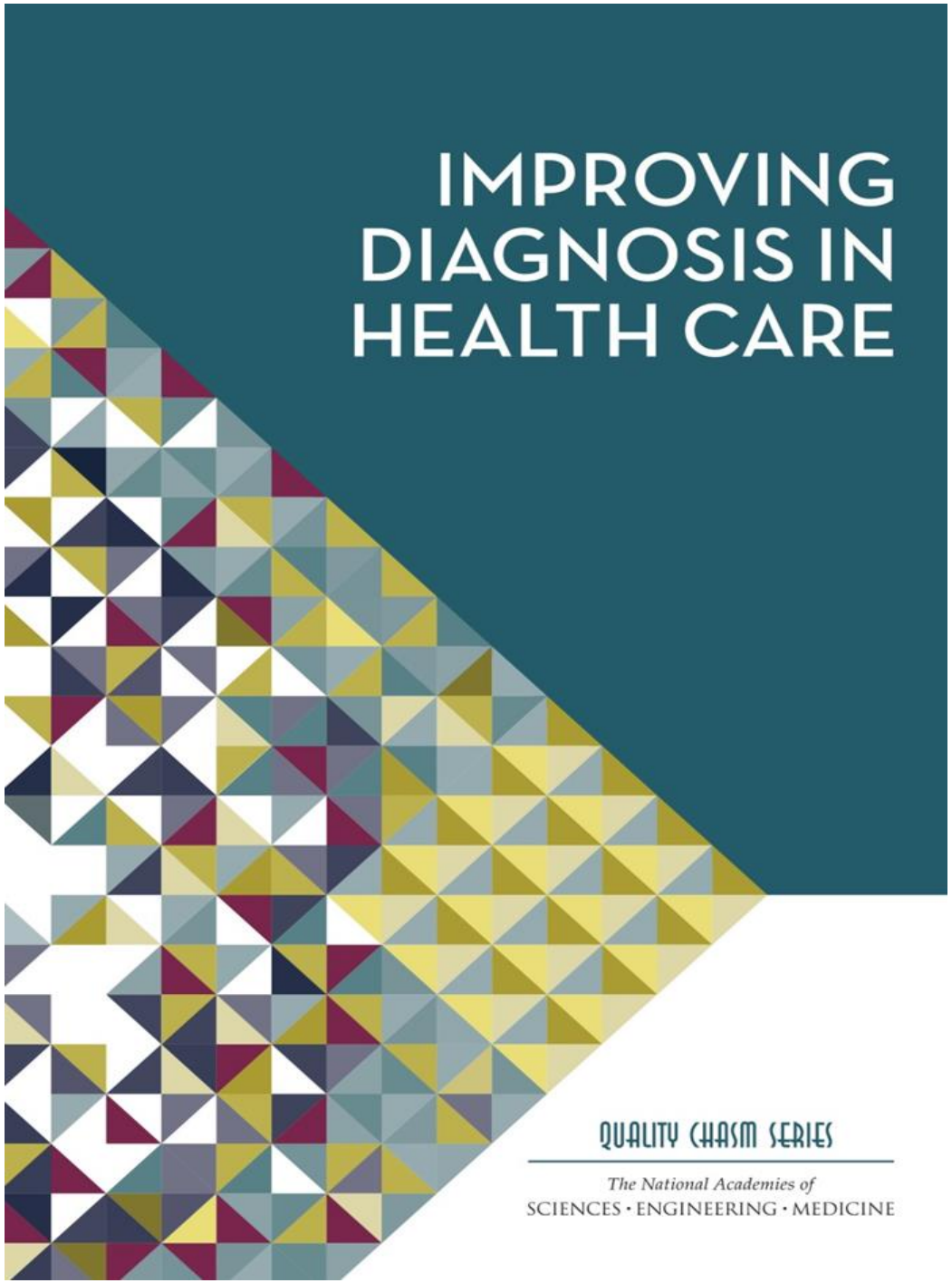


Institute for Healthcare Improvement NPSF

TOGETHER FOR SAFER CARE

Patient Identified Factors

Institute for Healthcare Improvement NPSF
TOGETHER FOR SAFER CARE



IOM Report September 2015

Don Berwick

Former President and CEO
Institute for Healthcare Improvement (IHI)
Former Director Centers for Medicare & Medicaid Services

The Boston Globe

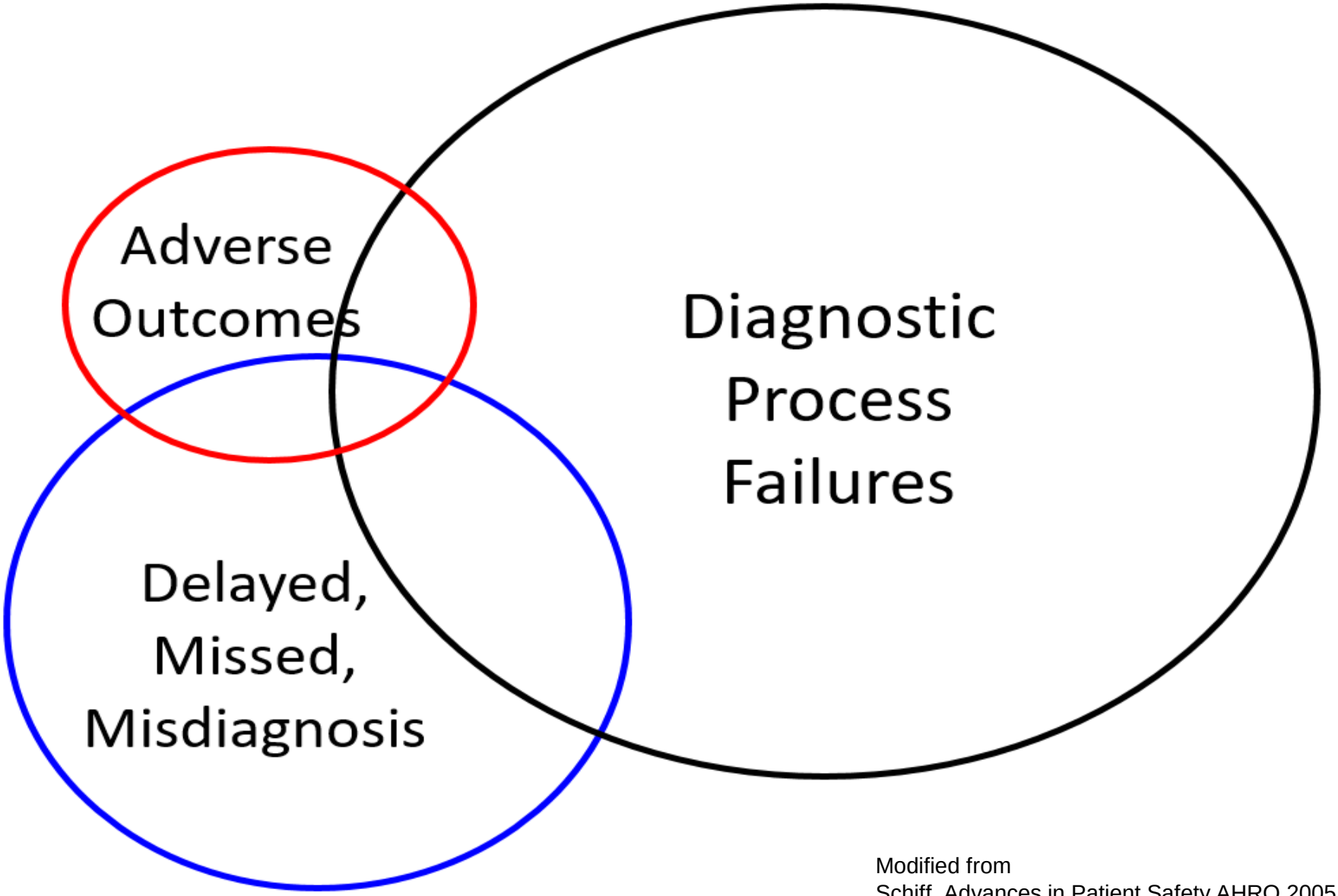
Genius diagnosticians make great stories, but they don't make great health care.

The idea is to make accuracy reliable, not heroic

Don Berwick

Boston Globe 7/14/2002

What is a Diagnosis Error?



Modified from
Schiff Advances in Patient Safety AHRQ 2005,
Schiff & Leape Acad Med 2012

Diagnosis and diagnostic errors: time for a new paradigm

Gordon D Schiff

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Accepted 22 August 2013

It looks like diagnosis triggers may be gaining traction. Building on their earlier efforts,[1 2] a team of investigators based in Houston reports (in the current issue of *BMJ Quality & Safety*) on their latest effort to apply electronic screens—so called 'triggers'—to large clinical databases, to identify cases of potential diagnostic errors.[3] They searched nearly 300 000 patients' records over a 12-month period at two large health systems with comprehensive electronic health records. They sought patients who had one of four 'red flag' findings for prostate or colon cancer—elevated prostate specific antigen (PSA), positive fecal occult blood test (FOBT), rectal bleeding (haematochezia), and iron deficiency anaemia. They then used a refined electronic algorithm to cull out patients who (1) were already known to have prostate or colorectal cancer, or (2) had evidence of appropriate follow-up testing or referral. This process left roughly 1500 patients with one of the four red flags potentially unaddressed. Thus, searching an enormous haystack of 300 000 patients, they found roughly 1500 possible 'needles'–patients who may have had their diagnosis of colon or prostate cancer delayed or overlooked entirely.

the outpatient systems of care obviously did not. Since there is no reason to believe their findings are not broadly representative of ambulatory care in general (and the fact that both the institutions had advanced electronic systems should, in theory, put them in a better position for reliable follow-up than those lacking such capability);, the findings mean that healthcare diagnosis, as measured by this one metric at least, is a long way from *six-sigma* quality (defined as one defect per 3.4 million). This study's rate translates into roughly 13 600 defects per 3.4 million patients. While one could quibble with some of the arbitrary cut-off intervals chosen for this study—a colonoscopy 61 days after a positive FOBT was failed care, whereas, one after 59 days was not; similarly with 91 vs 89 days for follow-up of an elevated PSA—the study unquestionably highlights undesirable delays that more efficient and more reliable care should be able to avoid.

The next important consideration to ponder is whether and how such retrospective 'triggers' can be used to minimise diagnostic errors prospectively. As we have noted previously, prospectively applying such triggers as safeguards to 'find and fix' actual or potential diagnostic errors and

BMJ Quality and Safety 2013

HEALTH CARE REFORM

Diagnostic Error in Medicine

Analysis of 583 Physician-Reported Errors

Gordon D. Schiff, MD; Omar Hasan, MD; Seijeoung Kim, RN, PhD; Richard Abrams, MD; Karen Cosby, MD; Bruce L. Lambert, PhD; Arthur S. Elstein, PhD; Scott Hasler, MD; Martin L. Kabongo, MD; Nela Krosnjar; Richard Odwazny, MBA; Mary F. Wisniewski, RN; Robert A. McNutt, MD

Background: Missed or delayed diagnoses are a common but understudied area in patient safety research. To better understand the types, causes, and prevention of such errors, we surveyed clinicians to solicit perceived cases of missed and delayed diagnoses.

Methods: A 6-item written survey was administered at 20 grand rounds presentations across the United States and by mail at 2 collaborating institutions. Respondents were asked to report 3 cases of diagnostic errors and to describe their perceived causes, seriousness, and frequency.

Results: A total of 669 cases were reported by 310 clinicians from 22 institutions. After cases without diagnostic errors or lacking sufficient details were excluded, 583 remained. Of these, 162 errors (28%) were rated as major, 241 (41%) as moderate, and 180 (31%) as minor or insignificant. The most common missed or delayed diagnoses were pulmonary embolism (26 cases [4.5% of total]), drug reactions or overdose (26 cases [4.5%]), lung cancer (23 cases [3.9%]), colorectal cancer (19 cases [3.3%]), acute coronary syndrome (18 cases [3.1%]), breast cancer (18 cases [3.1%]), and stroke (15 cases [2.6%]). Errors occurred most frequently in the testing phase (failure to order, report, and follow-up laboratory results) (44%), followed by clinician assessment errors (failure to consider and overweighing competing diagnosis) (32%), history taking (10%), physical examination (10%), and referral or consultation errors and delays (3%).

Conclusions: Physicians readily recalled multiple cases of diagnostic errors and were willing to share their experiences. Using a new taxonomy tool and aggregating cases by diagnosis and error type revealed patterns of diagnostic failures that suggested areas for improvement. Systematic solicitation and analysis of such errors can identify potential preventive strategies.

Arch Intern Med. 2009;169(20):1881-1887

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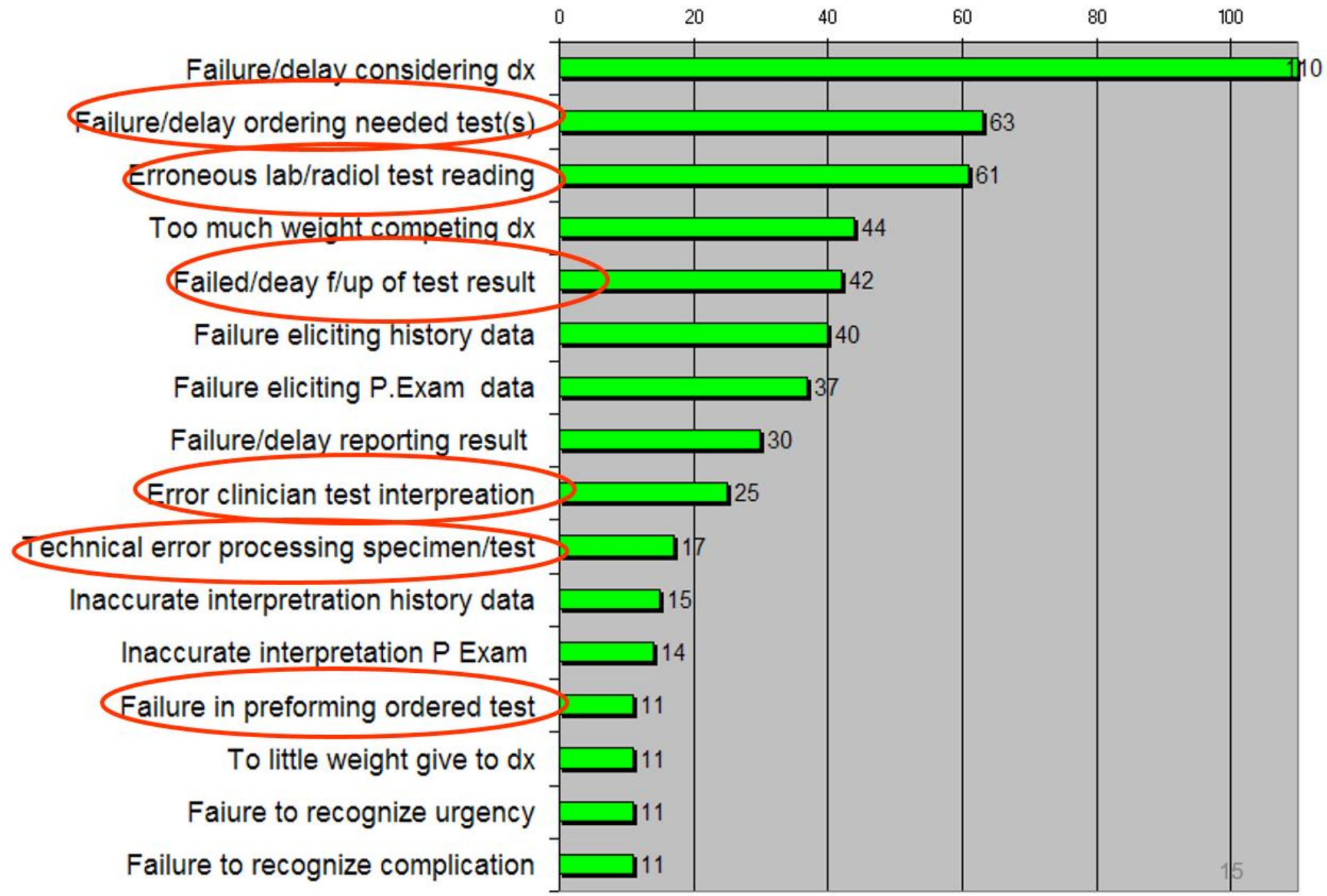
ERRORS RELATED TO DELAYED or missed diagnoses are a

cians are justifiably reluctant, and often defensive, about judging their own or

What went wrong: DEER Taxonomy Localization



Pre-analytical errors: their impact and how to minimize them

Kaushik & Green 2014

	Time	Error
1.	Before specimen collection	a. Inappropriate test requested or correct test not ordered
		b. Patient identification error
		c. Inadequate patient preparation
		d. Inadequate collection of patient information (medications, smoking, heavy exercise, etc.)
2.	During specimen collection	a. Inadequate specimen volume / Inappropriate blood to anticoagulant ratio
		b. Clotting or hemolysis of specimen due to inappropriate tube mixing
		c. Inappropriate specimen container
		d. Contamination from infusion route
		e. Incorrect order of draw
3.	After specimen collection	a. Specimen labeling error
		b. Improper specimen transport and storage conditions (time and temperature)
		c. Improper centrifugation time or speed

Pre-analytical errors:
their impact and how to minimize them

Kaushik & Green 2014

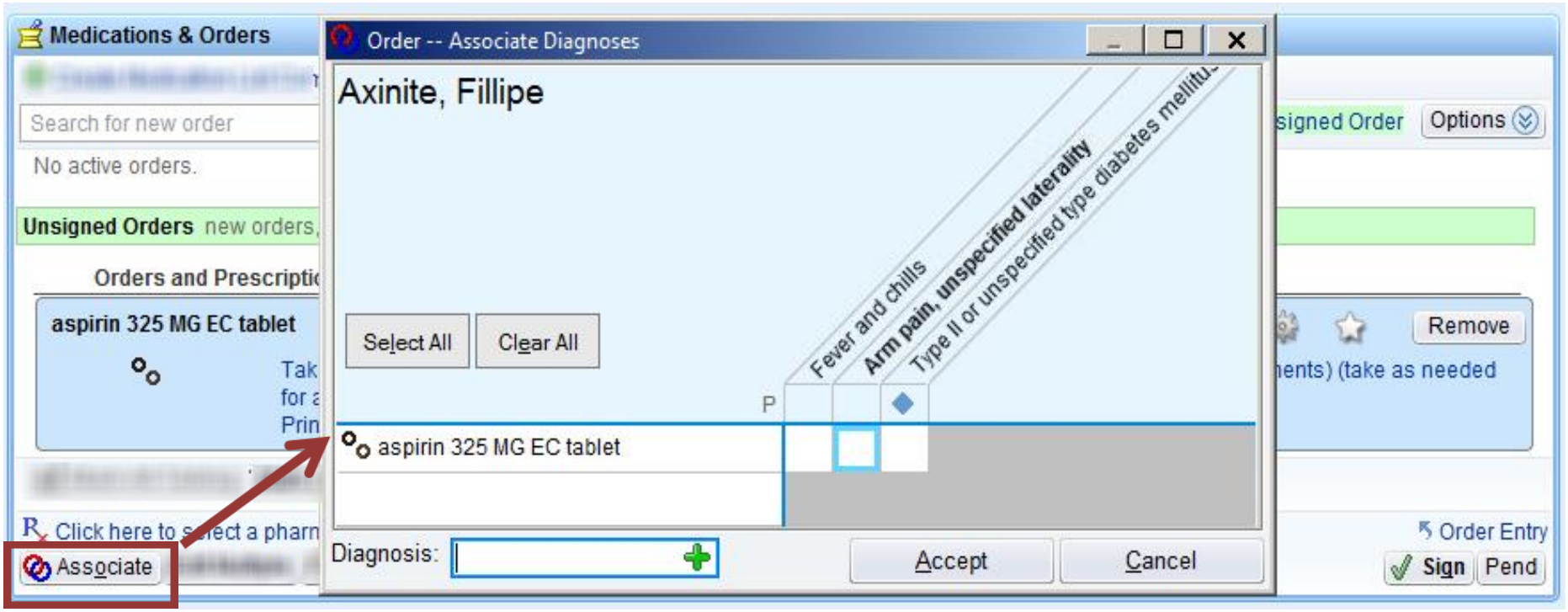
	Preanalytical error	Most common causes	Possible consequences	Best practices to minimize future errors
1.	Patient misidentification (incorrectly labeled tubes or incorrectly filled forms)	Inadequate data on test requisition form. Missing patient identifiers. Labeling specimen container away from bedside.	Mishandled therapy (e.g. wrong blood transfusion leading to acute hemolytic reaction). Specimen collection from wrong patient leading to delayed diagnosis or misdiagnosis.	Bar-coded wristbands. Use at least two patient identifiers while taking blood specimens.[3] Use biometric information (fingerprints, iris scanning).[18] Check requisitions against results. Label the specimen container immediately after specimen collection.
2.	Lipemic specimens	Test collection after heavy meals. Pre-existing metabolic disorder.	Interference of fat with optical reading of instrument, wrong electrolyte values	Prepare patient properly before specimen collection (overnight fasting). Specify patient condition (e.g. hyperlipoproteinemia) on test requisition form.
3.	Hemolysis	Forcing blood through needle of syringe. Collecting blood through intravenous line. Vigorous shaking of specimen. Centrifuging specimen before clotting.	Falsely high values of AST, potassium and LDH. Interference with spectrophotometric assays.[18]	Avoid vigorous mixing/agitation of blood specimen. Do not apply tourniquet for more than one minute since this can cause localized stasis and rupture of red blood cells. Prefer closed system for blood collection. Use transfer devices to transfer blood from syringe. Use luer-lok access device and discard tube when drawing from line.
4.	Incorrect specimen volume	Incorrect phlebotomy technique. Difficult venous access (pediatric patients, debilitated patients).	Erroneous lab result due to improper additive-to-blood ratio. Specimen rejection. Redraws.	Fill evacuated blood collection tubes to the stated draw volume.
5.	Clotted plasma specimen	Inappropriate mixing of tubes	False leucopenia Aberrant red cell indices. Instrument downtime due to probe clogging.	Follow manufacturer's guidelines for tube mixing.

Upstream

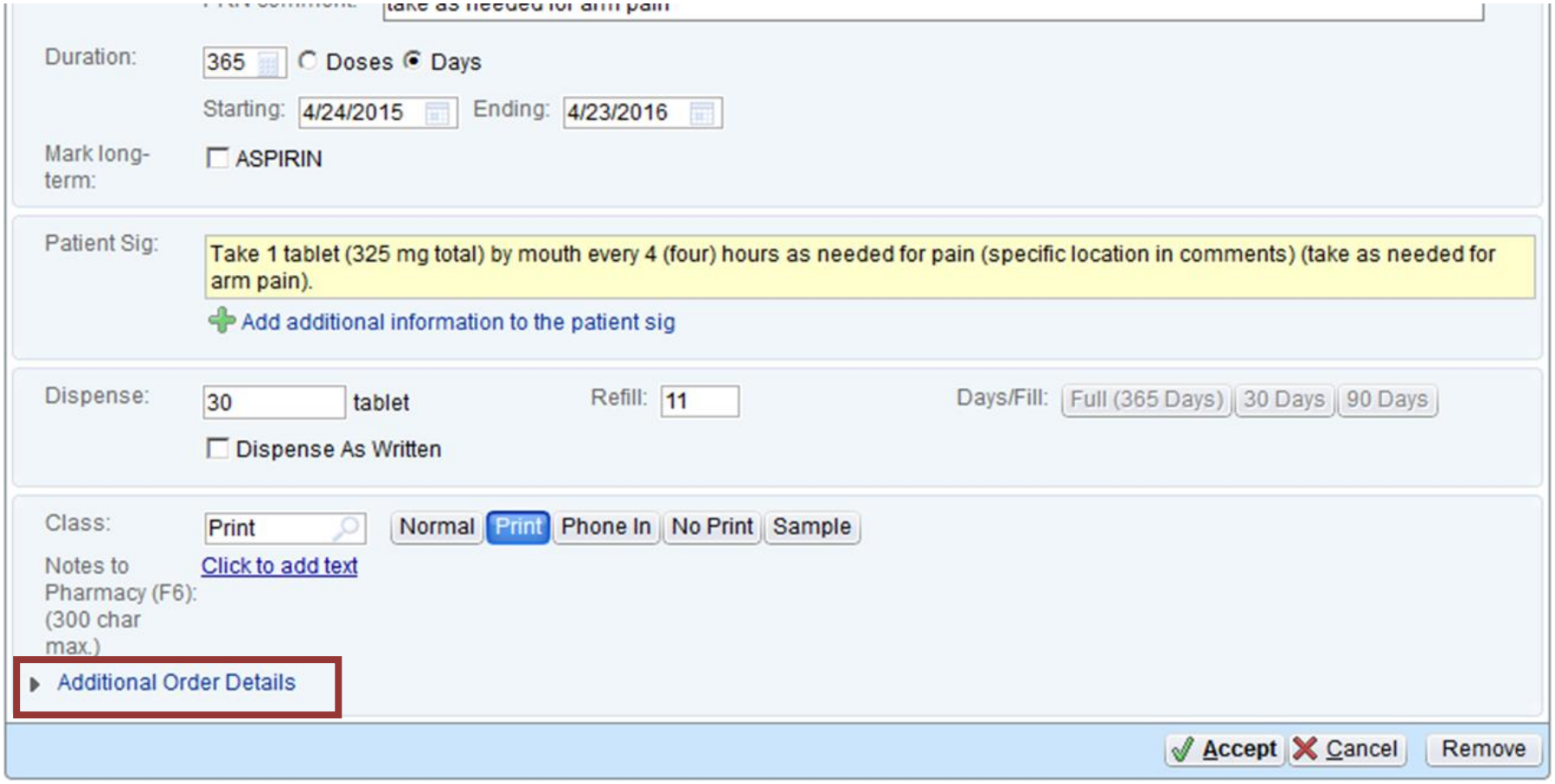
Decision Support/Reliability/Appropriateness

- Selection (which test)
  - Indications (why)
- Appropriateness
- Sequencing
  Prior testing
- Strategic considerations
- Thresholds
- Specimen collection/technique
- Timing collection
- Patient Preparation
- Transport
- Competing contraindicating factors
- Pt History
  - Accurately Collected/Communicate
- Patient preferences
- Alternatives
- Marginal Benefit
- Patient explanation/education
- Financial considerations
- Test Restrictions

Medication / Diagnosis Associations



Documenting Indications



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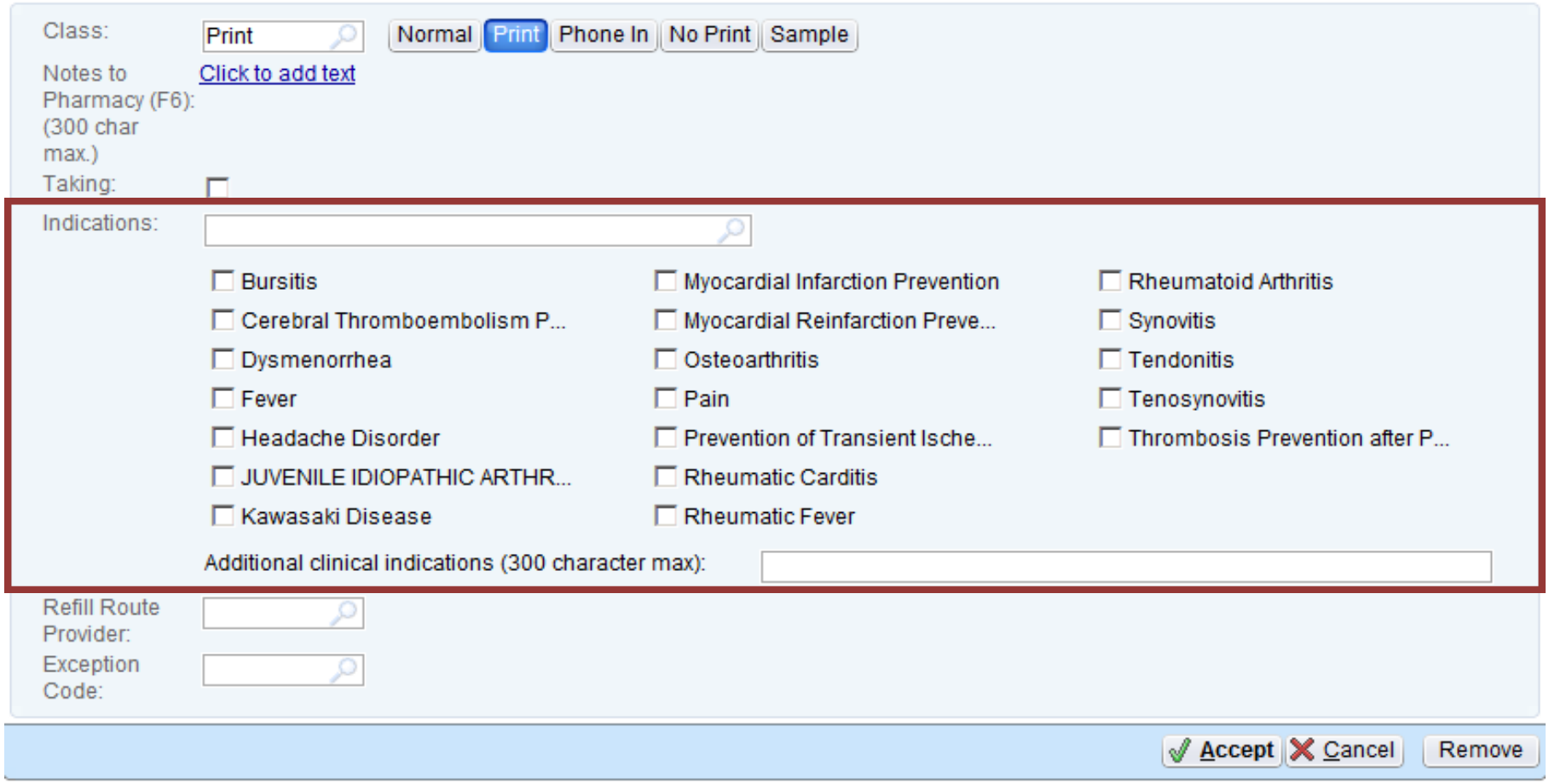

Incorporating Indications into Medication Ordering — Time to Enter the Age of Reason

Gordon D. Schiff, M.D., Enrique Seoane-Vazquez, Ph.D., and Adam Wright, Ph.D.

An 1833 article in the *Boston Medical and Surgical Journal* (forerunner of the *New England Journal of Medicine*) explained why prescriptions should be written in Latin to protect patients from knowledge of the names of and indications for the prescribed drugs:

"The question is often asked, why physicians do not write . . . prescriptions in English. The answer is obvious — that if they did, the patient would often be less benefited than he now is. There are very few minds which have sufficient firmness, during the continuance of disease, to reason calmly on the probable effects of remedies, and to compare their wonted action . . . with the indication to be fulfilled in the particular case. . . . The only state in which the mind can rest . . . during severe illness, is that of implicit reliance in the skill of the physician, and an entire acquiescence in the course adopted, without the slightest question or argument."[1]

In our current era of transparency, we add to each prescription an ingredient that's currently conspicuously missing: the right indication. This pivotal element affects and complements the other five, and considering it a sixth "right" would inform and enhance the safety of each prescription. With most prescriptions now being written electronically, this addition is particularly timely, since electronic medication ordering provides the vehicle for incorporating the indication into prescribing — and is handicapped in various ways without it.

Indications-based prescribing can contribute to better prescribing and medication use in multiple, synergistic ways (see table). First, when medication choices are narrowed to those indicated for a specific problem, decisions are much less prone to error. Staff and patients will be able to more easily recognize any mismatches and intercept prescribing or dispensing errors. Properly designed ordering systems could, for example, prevent common errors related to drugs whose reason each medication is being prescribed. Having this knowledge has been shown to be associated with better adherence and fewer errors,[2] yet patients often do not know the indications for some or all of their medications.[3] Pharmacists, visiting nurses, and caregiving relatives also need this information, but they are often even more in the dark about the reason for a given prescription. Presented with a choice, most patients prefer instructional leaflets and prescription labels that include indications to those that don't include indications.[4] Knowledge of the indication can also empower patients to question the necessity of a medication.

Third, prescribers need and want help choosing the best drugs for their patients' problems. Busy clinicians may not have time to look up recommended choices whenever they encounter problems beyond the limited repertoire they can hold in their heads. How many physicians can keep up with and recall the current regimen for *Helico-*

American Journal of Health-System Pharmacy (AJHP) April 2018

Incorporating medication indications into the prescribing process

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Pamela Neri, M.S., Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, and Partners Healthcare, Somerville, MA.

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Mary G. Amato, Pharm.D., M.P.H., Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, and MCPHS University, Boston, MA.

Adam Wright, Ph.D., Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, and Harvard Medical School, Boston, MA.

Sam Karmiy, B.S., Partners Healthcare, Somerville, MA.

Sarah McCord, M.L.I.S., M.P.H., MCPHS University, Boston, MA.

Enrique Seoane-Vazquez, Ph.D., School of Pharmacy, Chapman University, Irvine, CA.

Tewodros Eguale, Ph.D., M.D., Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, and MCPHS University, Boston, MA.

Rosa Rodriguez-Monguio, Ph.D., M.S., Medication Outcomes Center, University of California San Francisco, San Francisco, CA.

David W. Bates, M.D., M.Sc., Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, and

Purpose. The incorporation of medication indications into the prescribing process to improve patient safety is discussed.

Summary. Currently, most prescriptions lack a key piece of information needed for safe medication use: the patient-specific drug indication. Integrating indications could pave the way for safer prescribing in multiple ways, including avoiding look-alike/sound-alike errors, facilitating selection of drugs of choice, aiding in communication among the healthcare team, bolstering patient understanding and adherence, and organizing medication lists to facilitate medication reconciliation. Although strongly supported by pharmacists, multiple prior attempts to encourage prescribers to include the indication on prescriptions have not been successful. We convened 6 expert panels to consult high-level stakeholders on system design considerations and requirements necessary for building and implementing an indications-based computerized prescriber order-entry (CPOE) system. We summarize our findings from the 6 expert stakeholder panels, including rationale, literature findings, potential benefits, and challenges of incorporating indications into the prescribing process. Based on this stakeholder input, design requirements for a new CPOE interface and workflow have been identified.

Conclusion. The emergence of universal electronic prescribing and content knowledge vendors has laid the groundwork for incorporating indications into the CPOE prescribing process. As medication prescribing moves in the direction of inclusion of the indication, it is imperative to design CPOE systems to efficiently and effectively incorporate indications into prescriber workflows and optimize ways this can best be accomplished.

Keywords: CPOE, drug safety, medication errors, patient-centered care, patient safety, prescription drug indications

Am J Health-Syst Pharm. 2018; 75:e305-14

For nearly 4 decades, multiple or- the process of prescribing and dis-

Search problem or drug

Search

Order by Problem:

Active Problems

- Migraine Headaches
- HIV Disease
- Depression
- Asthma
- Insomnia

Inactive Problems

- Gonorrhea
- Cough
- Acne

Search problem or drug

Search

Order by Problem:

Active Problems

- **Migraine Headaches**
- HIV Disease
- Depression
- Asthma
- Insomnia

Active Medications:
Naproxen tablet (Aleve) 220mg : 1 po bid PRN headaches

Inactive Problems

- Gonorrhea
- Cough
- Acne

Search problem or drug

Search

Order by Problem:

Active Problems

- Migraine Headaches
  - *Prevention*
  - *Treatment*
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Search problem or drug

Search

Show Problems >

Migraine Headache Prevention Drug Order

Suggested Choice:

Metoprolol Succinate (Toprol-XL)
Beta-Blocker

Alternatives:

Other Beta-Blockers Show Drugs

Non Beta-Blockers Show Drugs

Not Recommended:

Amitriptyline (Elavil)

Divalproex Sodium Extended-Release (Depakote ER)

Topiramate (Topamax)

Feedback Live Chat

Patient's Active Migraine Drugs:

Drug	Started	Actions
Naproxen tablet (Aleve) 220mg : 1 po bid PRN headaches	12/1/2015	Refill Edit Stop

Patient's Inactive Migraine Drugs:

Drug	Dates Taken	Reason Stopped
Amitriptyline (Elavil) 25mg tablet: 1 po qhs	12/1/2014 - 1/1/2015	Patient didn't tolerate - caused dizziness

Non-Pharmacologic Options:

- Biofeedback
- Relaxation
- Cognitive-behavioral therapy
- Acupuncture
- Transcutaneous electrical nerve stimulation

Search

Show Problems >

Migraine Headache Prevention Drug Order

Suggested Choice:

Metoprolol Succinate (Toprol-XL)
Beta-Blocker

✓ 2012 Guidelines. Level A evidence *(medications with established efficacy)*
✓ Preferred because it is a selective beta-blocker
– Covered by insurance, **$**
– FDA Status: off-label
– **Other Factors Considered:** Potential DDIs with current medications, past treatment failures, last BPs

Alternatives:

Other Beta-Blockers — Show Drugs

Non Beta-Blockers — Show Drugs

Not Recommended:

- Amitriptyline (Elavil)
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Feedback | Live Chat

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Show Problems >

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Topiramate (Topamax)

✕ **Potential DDI:** Caution is warranted when darunavir is administered with valproic acid as there is a potential for altered concentrations of darunavir. Decreased antiretroviral concentrations may lead to a reduction of antiretroviral efficacy and the potential development of viral resistance

- Covered by insurance, **$$**
- FDA Status: labeled

Feedback Live Chat

Patient's Active Migraine Drugs:

Drug	Started	Actions
Naproxen tablet (Aleve) 220mg : 1 po bid PRN headaches	12/1/2015	Refill Edit Stop

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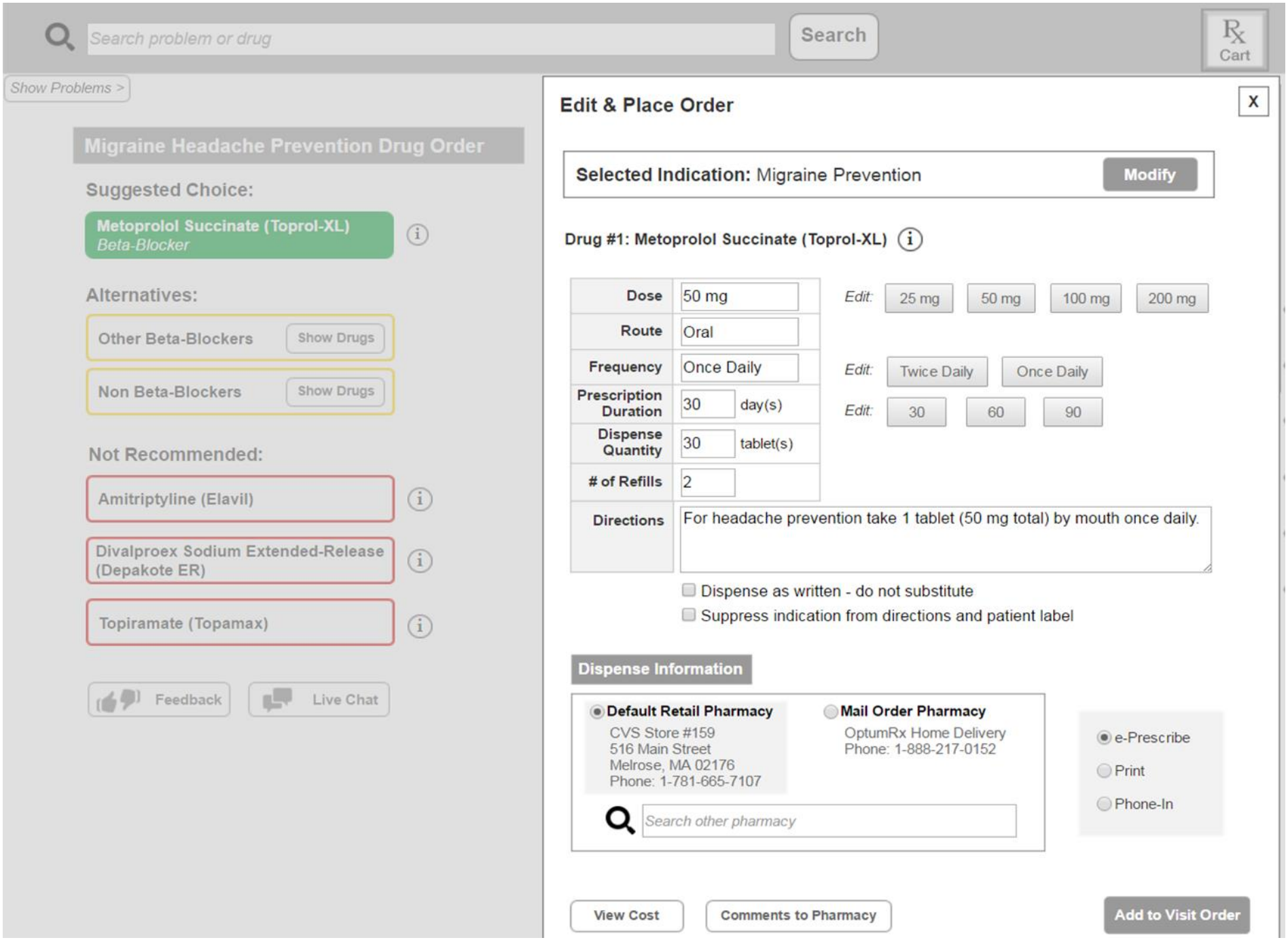
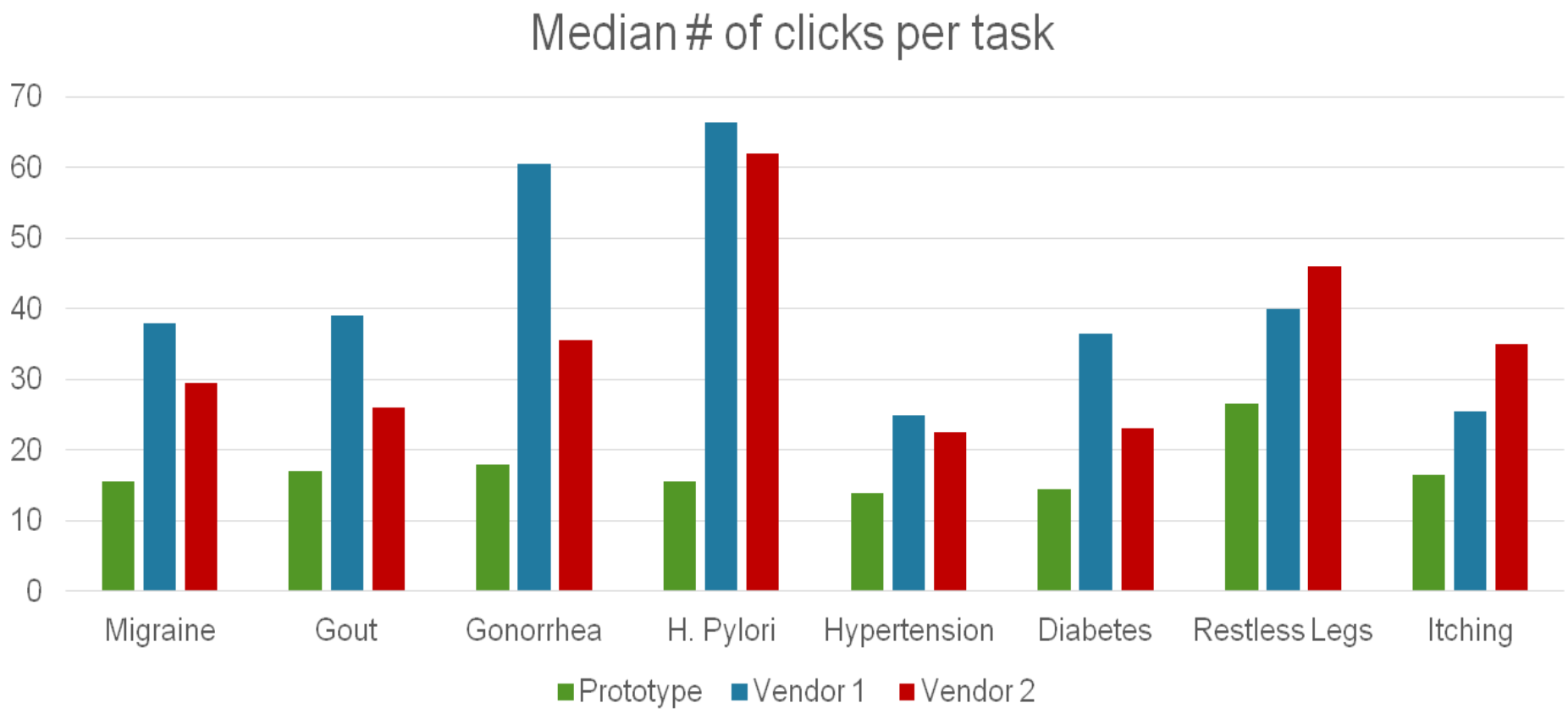

Search problem or drug
Search
Rx Cart
Show Problems >
Migraine Headache Prevention Drug Order
Suggested Choice:
Metoprolol Succinate (Toprol-XL)
Beta-Blocker
Alternatives:
Other Beta-Blockers
Show Drugs
Non Beta-Blockers
Show Drugs
Not Recommended:
Amitriptyline (Elavil)
Divalproex Sodium Extended-Release (Depakote ER)
Topiramate (Topamax)
Feedback
Live Chat
Edit & Place Order
X
Selected Indication: Migraine Prevention
Modify
Drug #1: Metoprolol Succinate (Toprol-XL)
Dose
50 mg
Edit:
25 mg
50 mg
100 mg
200 mg
Route
Oral
Frequency
Once Daily
Edit:
Twice Daily
Once Daily
Prescription Duration
30
day(s)
Edit:
30
60
90
Dispense Quantity
30
tablet(s)
# of Refills
2
Directions
For headache prevention take 1 tablet (50 mg total) by mouth once daily.
Dispense as written - do not substitute
Suppress indication from directions and patient label
Dispense Information
Default Retail Pharmacy
CVS Store #159
516 Main Street
Melrose, MA 02176
Phone: 1-781-665-7107
Mail Order Pharmacy
OptumRx Home Delivery
Phone: 1-888-217-0152
Search other pharmacy
e-Prescribe
Print
Phone-In
View Cost
Comments to Pharmacy
Add to Visit Order


Median # of clicks per task
70
60
50
40
30
20
10
0
Migraine
Gout
Gonorrhea
H. Pylori
Hypertension
Diabetes
Restless Legs
Itching
Prototype
Vendor 1
Vendor 2

Upstream

Decision Support/Reliability/Appropriateness

- Selection (which test)
  - Indications (why)
- Appropriateness
- Sequencing
  Prior testing
- Strategic considerations
- Thresholds
- Specimen collection/technique
- Timing collection
- Patient Preparation
- Transport
- Competing contraindicating factors
- Pt History
  - Accurately Collected/Communicate
- Patient preferences
- Alternatives
- Marginal Benefit
- Patient explanation/education
- Financial considerations
- Test Restrictions

Downstream

- Communicating result
- Reliable handoff to right person(s)
  - Not just hot potato


ELECTRONIC
HOT POTATO
GAME
THE MUSICAL
POTATO-
PASSING
GAME!
HOT POTATO

Downstream

- Communicating result
- Reliable handoff to right person(s)
  - Not just hot potato
  - Timing, method
  - Interruptive vs. asynchronous
- Acknowledgement
- Action
- Documentation
- Communication w/ patient; comments
- Tracking/closing loop

- Interpreting Understanding
- Bayesian weighing
- Repeat Testing: for f/up,
- Repeating: inadequate prep
- 0pen notes
- Degree confidence
- When to question; get 2nd lab, other opinion

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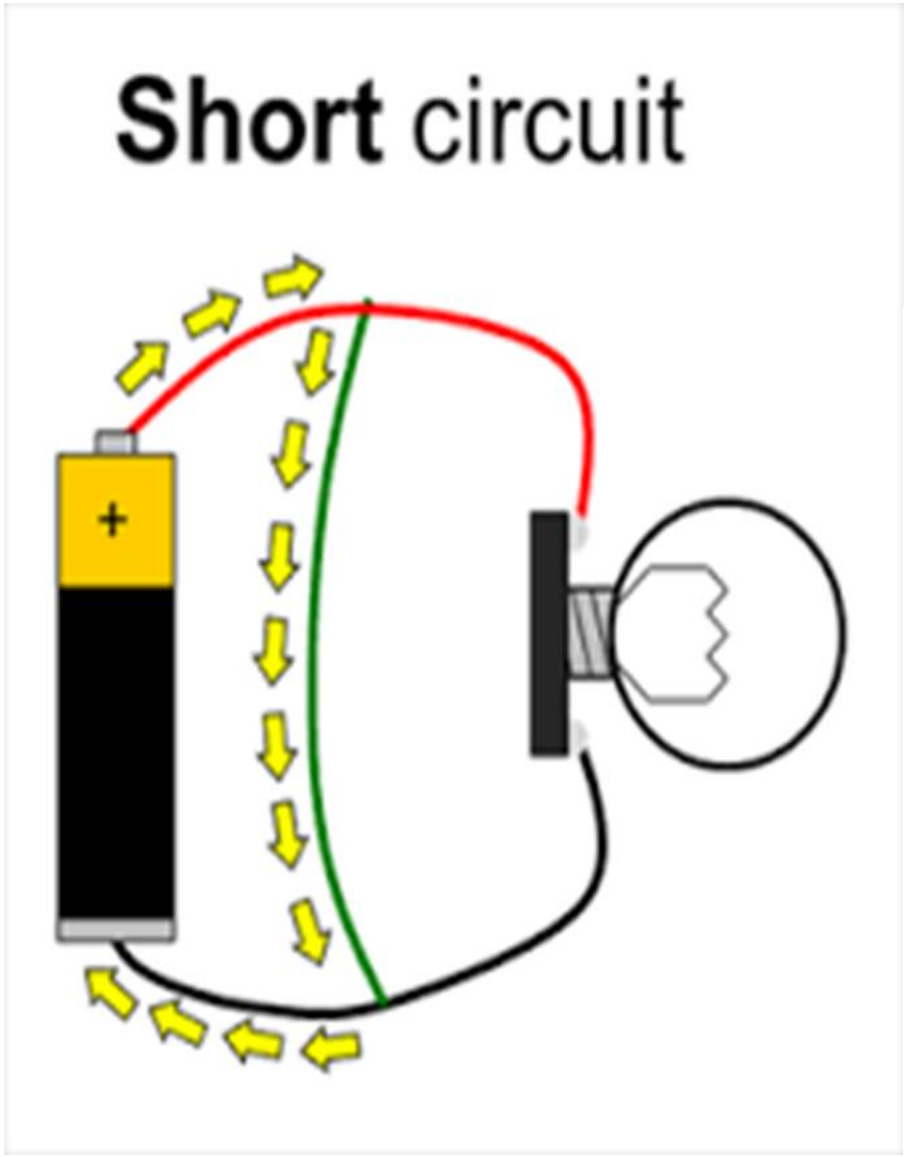
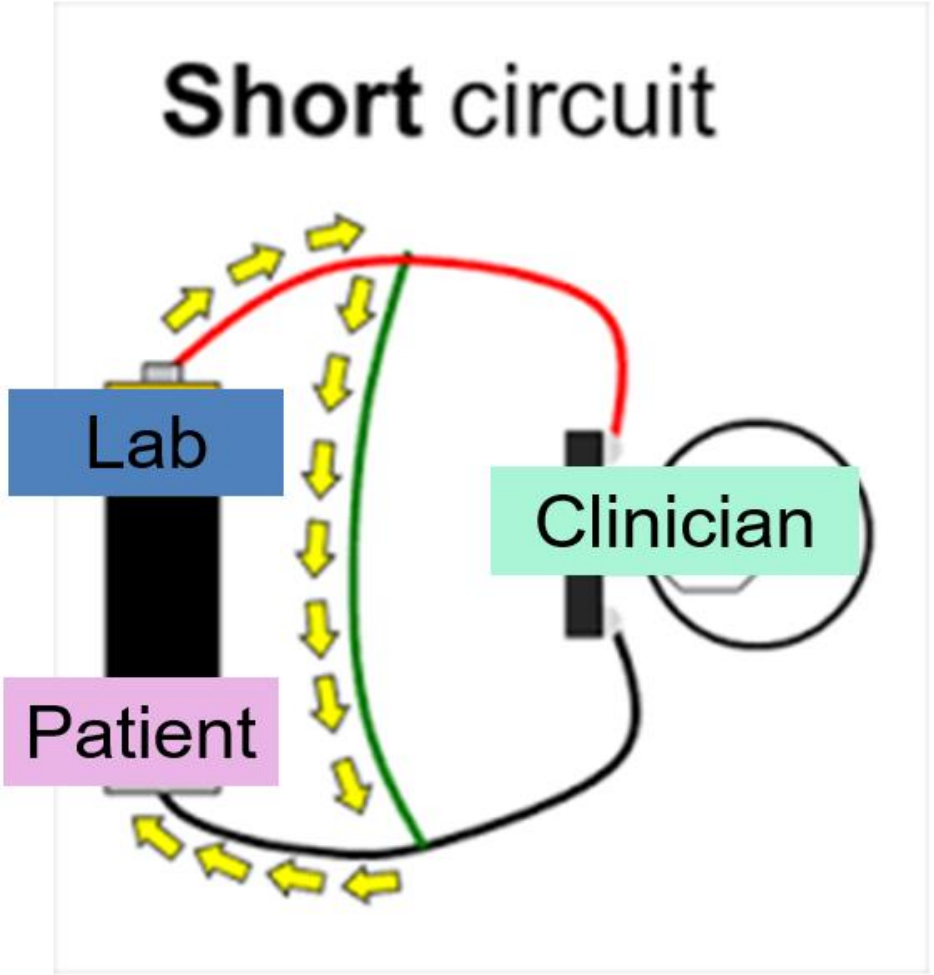

Short circuit
+

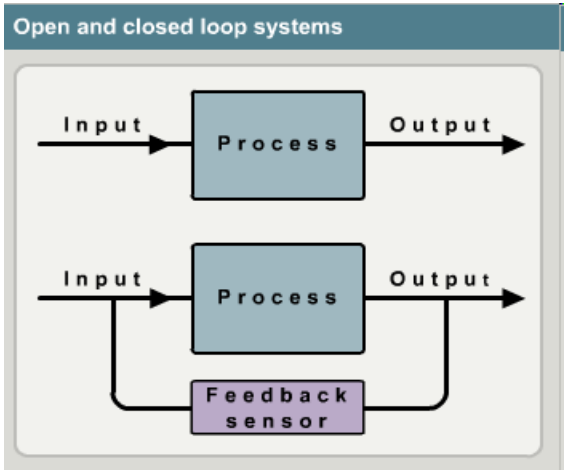

Short circuit
Lab
Clinician
Patient

Recognizing/Addressing Quality Barriers

- Lack of evidence
- Lack of knowledge (of evidence)
- Conflicting information/recommendations
- Poorly designed clinical decision support
  - Nuisance/false +, workflow/efficiency, feedback/learning
- Not (well) linked to patient-specific factors
- Unclear how to best account for patient factors
- Fumbled handoffs
- Rework /waste/manual nonautomated efforts
- Confusion; complexity
- Duplicated efforts

Need for closed-loop

- Fundamental engineering principle
  - Feedback information to recalibrate system
- Feedback from downstream clinician to upstream radiologist to gauge own efficacy and positively ensure acknowledgment of receipt and action
- Diagnosis in general open loop



Randomized Trial of Reducing Ambulatory Malpractice and Safety Risk

Results of the Massachusetts PROMISES Project

Gordon D. Schiff, MD,† Harry Reyes Nieva, BA,*†‡ Paula Griswold, MS,§ Nicholas Leydon, MPH, MBA,‖¶ Judy Ling, BA,‖ Frank Federico, RPh,# Carol Keohane, MS, RN,** Bonnie R. Ellis, BSN, RN,†† Cathy Foskett, BSN, RN,* E. John Orav, PhD,*†‡‡ Catherine Yoon, MS,* Don Goldmann, MD,†#‡‡ Joel S. Weissman, PhD,†‡‡§§ David W. Bates, MD, MSc,*†‡‡ Madeleine Biondolillo, MD,‖ and Sara J. Singer, PhD, MBA†‡‡‖‖*

Objective: Evaluate application of quality improvement approaches to key ambulatory malpractice risk and safety areas.

Study Setting: In total, 25 small-to-medium-sized primary care practices (16 intervention; 9 control) in Massachusetts.

Study Design: Controlled trial of a 15-month intervention including exposure to a learning network, webinars, face-to-face meetings, and coaching by improvement advisors targeting "3+1" high-risk domains: test result, referral, and medication management plus culture/communication issues evaluated by survey and chart review tools.

Data Collection Methods: Chart reviews conducted at baseline and postintervention for intervention sites. Staff and patient survey data collected at baseline and postintervention for intervention and control sites.

Principal Findings: Chart reviews demonstrated significant improvements in documentation of abnormal results, patient notification, documentation of an action or treatment plan, and evidence of a completed plan (all $P < 0.001$). Mean days between laboratory test date and evidence of completed action/treatment plan decreased by 19.4 days ($P < 0.001$). Staff surveys showed modest but nonsignificant improvement for intervention practices relative to controls overall and for the 3 high-risk domains that were the focus of PROMISES.

Conclusions: A consortium of stakeholders, quality improvement tools, coaches, and learning network decreased selected ambulatory safety risks often seen in malpractice claims.

Key Words: primary care, care improvement, satisfaction, patient safety, malpractice

(*Med Care* 2017;55: 797–805)

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Over the past decade, attention to patient safety and malpractice issues has increasingly focused on ambulatory, particularly primary care, settings.[1–5] Many ambulatory malpractice claims demonstrate preventable harm and recent studies have suggested that such cases may be less defensible than inpatient claims[6,7] pointing to significant opportunities for safer care. The ambulatory setting is rife with safety risks related to care characterized by high volumes, increasing production pressures, fragmented often poorly coordinated care, and diagnostic, handoff, and health information technology challenges.[6–9] Compared with inpatient facilities, ambulatory settings, particularly smaller offices lack safeguards, risk management support, and egulatory oversights.[5,10] Despite its importance, few rigorously evaluated interventions to improve ambulatory safety have been reported, with most more narrowly on specific domains such as medication errors.[11]

Guided by the perspective that the best way to reduce malpractice is to address problems that often underlie suboptimal care, the Agency for Healthcare Research and Quality-funded PROMISES (Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and

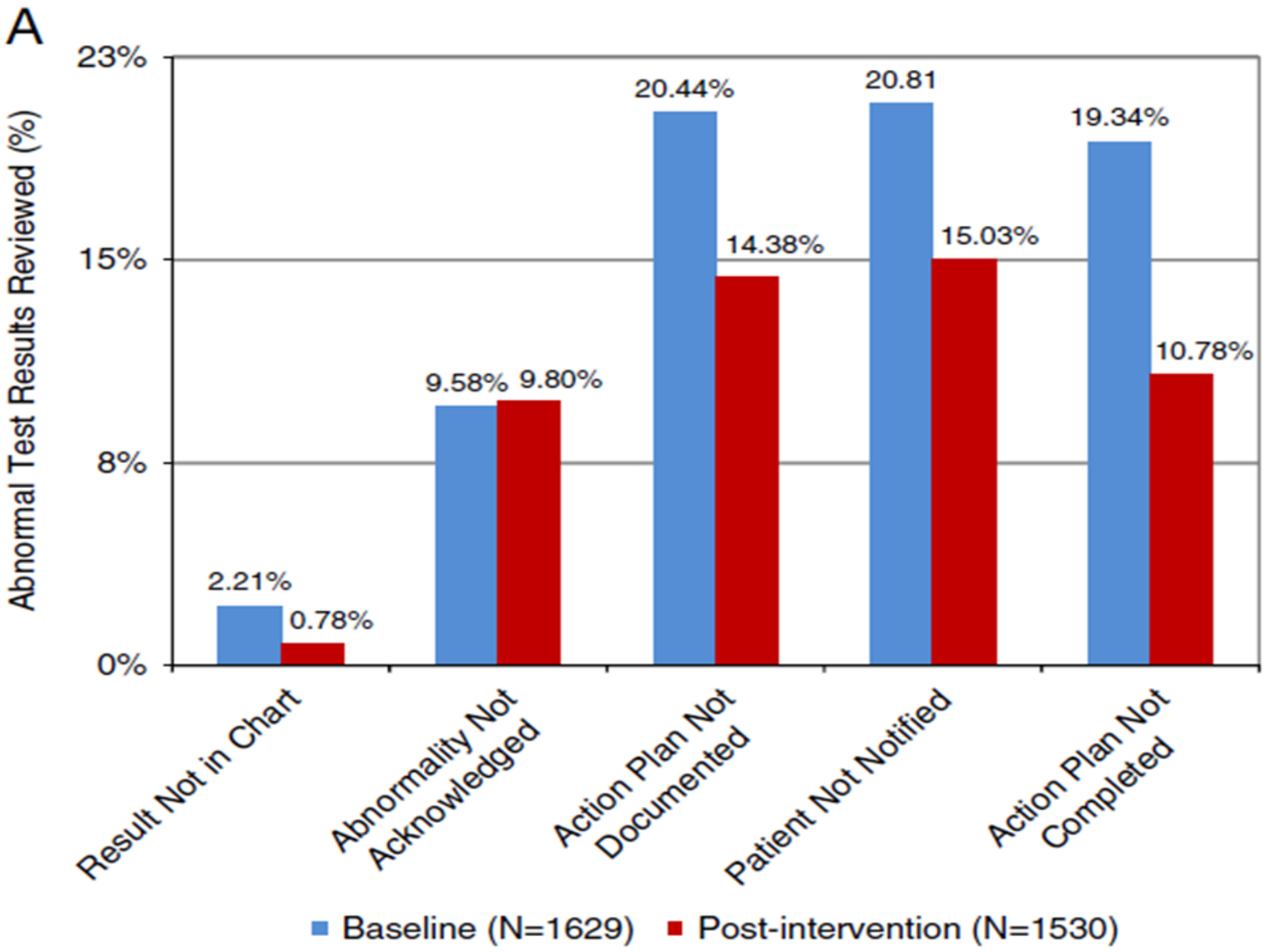
Schiff et al Medical Care 2017

Are Test Results Reliably Acknowledged and Acted on?

TSH	251	16%
Cr	572	37%
K	278	18%
INR	213	14%
PSA	148	10%
Guaiac+	10	1%
Abnl Colonspy	18	1%
Abnl Mamgrm	11	1%
Abnl Pap	4	0%
Pulm Nodule	22	1%
Abdom Mass	17	1%
	1544	

Result Found in Chart	97.1%
Abnormal Acknowledged	90.1%
Action Plan Documented	78.7%
Action Plan Completed	80.0%
Patient Notified	77.4%

Preliminary data PROMISES Project Unpublished 2012


A
Abnormal Test Results Reviewed (%)
23%
15%
8%
0%
2.21%
0.78%
9.58%
9.80%
20.44%
14.38%
20.81
15.03%
19.34%
10.78%
Result Not in Chart
Abnormality Not Acknowledged
Action Plan Not Documented
Patient Not Notified
Action Plan Not Completed
Baseline (N=1629)
Post-intervention (N=1530)

Mock-up of Monthly Automated Abnormal Primary Care Tracking Report (Generated from Lab/Vendor)

Patient Name	DOB	Flagged test	Previous value	Flagged Value	Most Recent	Code*	*Flag Criteria*	*Practice Chart Review*				
								Documented	*Acknow-ledged*	*Action Taken*	Patient Notified	**F/up Needed**
Doe, John	12/2/1961	K+	2/1/2018	**4/20/2018**	4/292018	4	*K+>5.4*					
			4.8	**5.7**	5							
			3/14/2018	**4/13/2018**	1/22/2013	4	*INR>4*					
		INR	3.2	**7**	2.5							
Smith, Mary,	10/15/1954	Cr	11/10/2016	**4/14/2018**		1	*Cr>1.8*					
			1	**3.2**								
			3/6/2018	**4/3/2018**								
Jones, Bill	7/16/1950	Na	142	**126**		1	*Na<129*					
			2/2/2018	**4/1/2018**								
Smith, Harry	11/1/1996	BUN	71	**65**		3	*BUN>26*					
				4/15/2018								
Hill, Meg	1/10/1956	BUN		**47**		1	*BUN>26*					
				4/1/2018	5/2/2018							
White, Mary	2/2/1965	TSH		**9.1**	8.4	2	*TSH>6*					
			3/10/2016	**4/2/2018**								
White, Joe	6/10/1955	Hb	14.1	**9.9**		1	*Hb<10.5*					

Mock-up of Monthly Automated Abnormal Primary Care Tracking Report (Generated from Lab/Vendor)

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								Documented	*Acknow-ledged*	*Action Taken*	Patient Notified	**F/up Needed**
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			4.8	**5.7**	5							
			3/14/2018	**4/13/2018**	1/22/2013	4	*INR>4*					
		INR	3.2	**7**	2.5							
Smith, Mary,	10/15/1954	Cr	11/10/2016	**4/14/2018**		1	*Cr>1.8*					
			1	**3.2**								
			3/6/2018	**4/3/2018**								
Jones, Bill	7/16/1950	Na	142	**126**		1	*Na<129*					
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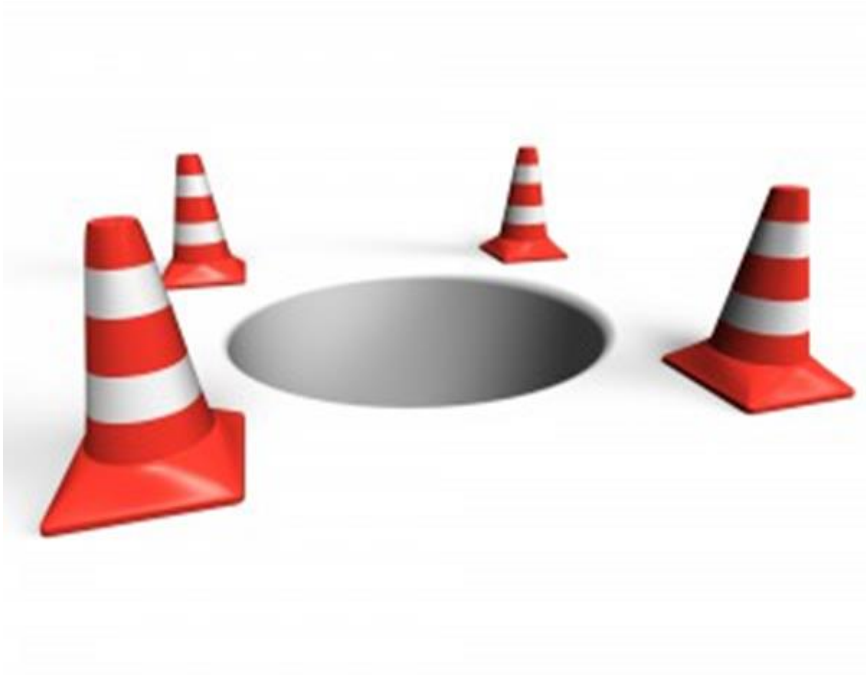
			3/10/2016	**4/2/2018**								
White, Joe	6/10/1955	Hb	14.1	**9.9**		1	*Hb<10.5*					

What is a **Diagnostic Pitfall**?



Clinical situations where patterns of, or vulnerabilities to errors leading to missed, delayed or wrong diagnosis

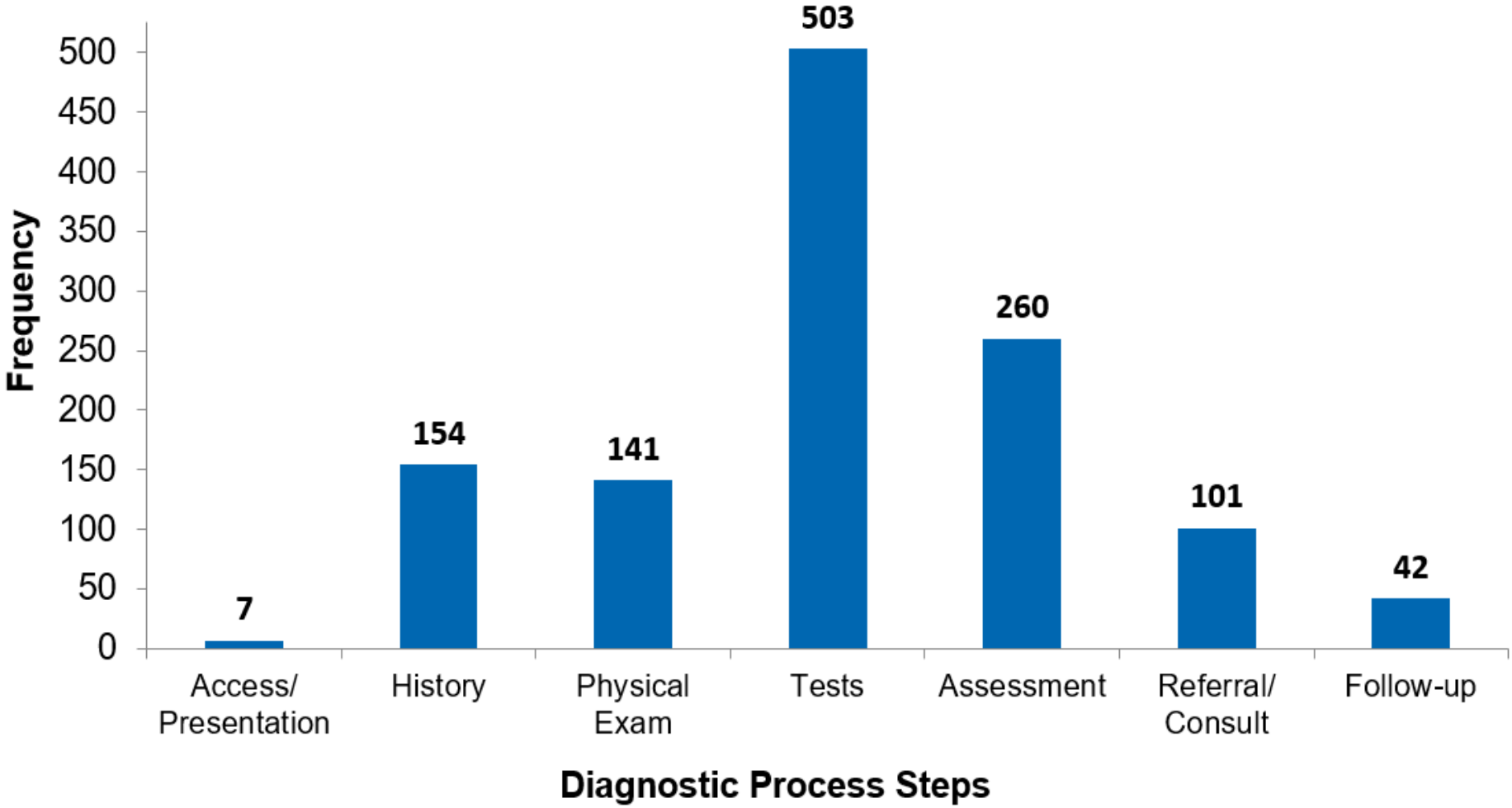
Diagnostic Error Evaluation and Research (DEER) Taxonomy

Where did it go wrong?		What went wrong?
Access/ Presentation	A	Failure/delay in presentation
	B	Failure/denied care access
History	A	Failure/delay in eliciting critical piece of history data
	B	Inaccurate/misinterpreted critical piece of history data
	C	Failure in weighing critical piece of history data
	D	Failure/delay to follow-up critical piece of history data
Physical Exam	A	Failure/delay in eliciting critical physical exam finding
	B	Inaccurate/misinterpreted critical physical exam finding
	C	Failure in weighing critical physical exam finding
	D	Failure/delay to follow-up critical physical exam finding
Tests (Lab/ Radiology)		***Ordering***
	A	Failure/delay in ordering needed test(s)
	B	Failure/delay in performing ordered test(s)
	C	Error in test sequencing
	D	Ordering of wrong test(s)
	E	Tests ordered wrong way
		Performance
	F	Sample mix-up/mislabeled (e.g. wrong patient/test)
	G	Technical errors/poor processing of specimen/test
	H	Erroneous lab/radiology reading of test
	I	Failed/delayed reporting of result to clinician
		Clinician Processing
	J	Failed/delayed follow-up of (abnormal) test result
	K	Error in clinician interpretation of test
Assessment		***Hypothesis Generation***
	A	Failure/delay in considering the diagnosis
		Suboptimal Weighing/Prioritizing
	B	Too little consideration/weight given to the diagnosis
	C	Too much weight on competing/coexisting diagnosis
		Recognizing Urgency/Complications
	D	Failure/delay to recognize/weigh urgency
	E	Failure/delay to recognize/weigh complications
Referral/ Consultation	A	Failure/delay in ordering referral
	B	Failure/delay obtaining/scheduling ordered referral
	C	Error in diagnostic consultation performance
	D	Failed/delayed communication/follow-up of consultation
Follow-up	A	Failure to refer patient to close/safe setting/monitoring
	B	Failure/delay in timely follow-up/rechecking of patient

Reliable Diagnosis Challenges (RDC) Taxonomy

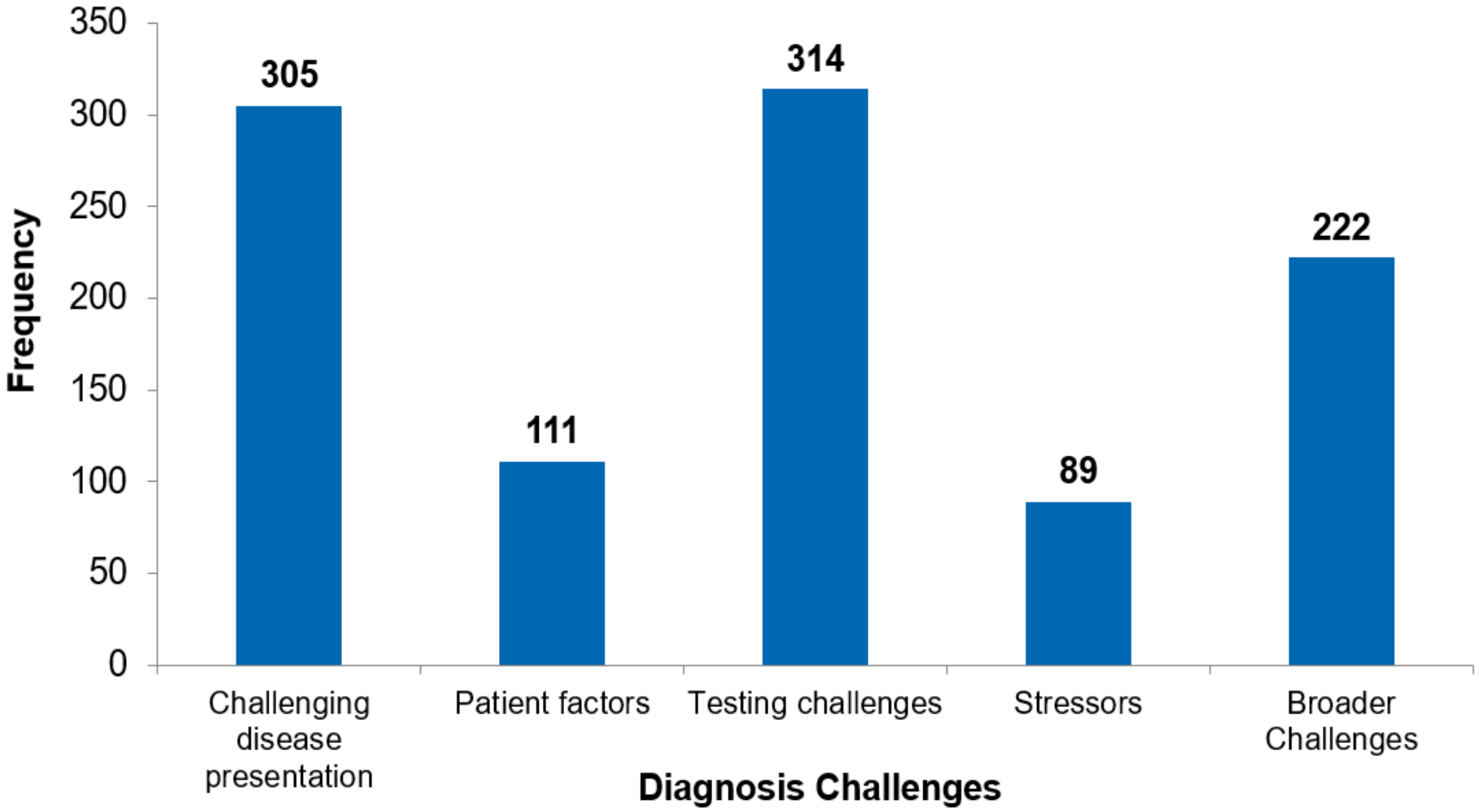
Challenge Category		Specific Challenge
Challenging Disease Presentation	A	Rare diagnosis
	B	Atypical presentation
	C	Nonspecific signs and symptoms
	D	Unfamiliar/outside specialty
	E	Masking/mimicking diagnosis
	F	Red herring misleading finding
	G	Rapidly progressive
	H	Slowly evolving
	I	Deceptively benign course
Patient Factors	A	Language/communication
	B	Signal:noise (noisy pts)
	C	Patient fails to share
	D	Patient fails to follow-up
Testing Challenges	A	Test availability, access, cost
	B	Logistical issues
	C	False positive/negative results
	D	Performance/interpretation
	E	Equivocal results/reports
	F	Test follow-up issues
Stressors	A	Time constraints
	B	Care Discontinuities
	C	Fragmentation of care
	D	Memory reliance/challenges
Broader Challenges	A	Recognition of acuity/severity
	B	Diagnosis of complication
	C	Recognizing failure to respond to treatment
	D	Diagnosis of underlying cause
	E	Recognizing misdiagnosis

Results – DEER Taxonomy Errors (n = 1208)



Schiff et al –Diagnostic Pitfalls Unpublished data 2018

Results - RDC Taxonomy Issues (n = 1041)



GENERIC TYPES of PITFALLS

- **Disease A repeatedly mistaken for Disease B**
  - Bipolar disease mistaken for depression
- **Failure to appreciate test/exam limitations**
  - Pt w/ breast lump and negative mammogram and/or ultrasound
- **Atypical presentation**
  - Addison's disease presenting with cognitive difficulties
- **Presuming chronic disease accounts for new symptoms**
  - Lung cancer: failure to pursue new/unresolving pulmonary sx in patient with pre-existing COPD
- **Overlooking drug, other environmental cause**
  - Pancreatitis from drug; carbon monoxide toxicity fail to consider
- **Failure to monitor evolving symptom**
  - Normal imagining shortly after head injury, but chronic subdural hematoma later develops

Diagnostic Pitfalls Project (Top 10 Diagnoses)

Diagnostic Pitfalls	Colon Cancer (N=46)	Lung Cancer (N=43)	Prostate Ca (N=34)	Breast Cancer (N=33)	MI (N=29)	Sepsis (N=16)	Stroke (N=16)	PE (N=11)	Thyroid Ca (N=7)	Melanoma (N=6)	Overall (N=241)
Failure to follow-up	10	14	16	14	6	-	-	-	4	4	28%
Limitations of test or exam not appreciate	5	12	8	14	12	-	4	2	3	2	26%
Disease A repeatedly mistaken for Disease	9	11	5	-	12	6	8	3	-	4	24%
Risk factors not adequately appreciated	10	-	15	4	7	-	-	3	-	-	16%
Atypical presentation	-	-	4	15	8	3	7	-	-	-	15%
Counter-dx cues overlooked (e.g. red flags	21	-	-	-	-	4	-	-	-	-	10%
Communication failures PCPs--specialists	7	4		4	3	-	-	-	-	-	7%
Issues surrounding referral	-		3		4	-	-	-	-	-	3%
Urgency not fully appreciated	-	-	-	-	-	4	2	-	-	-	2%
Chronic disease presumed as cause of new	-	-	-	-	-	3	1	-	-	-	2%
Miscommunication related to lab ordering	-	-	-	-	-	3		-	-	-	1%
Evolving symptoms not monitored	-	2	-	-	-	-	-	-	-	-	1%
Drug or environmental etiol overlooked	-	-	-	-	-	-	-	-	-	-	0%
Empiric Rx delaying/making recognition	-	-	-	-	-	-	-	-	-	-	0%
Diagnosis is rare or unfamiliar	-	-	-	-	-	-	-	-	-	-	0%
Symptoms are non-specific or vague	-	-	-	-	-	-	-	-	-	-	0%
Symptoms are intermittent	-	-	-	-	-	-	-	-	-	-	0%
Language-related communication failures	-	-	-	-	-	-	-	-	-	-	0%

Linking & Leveraging Lab and Pharmacy Data to Improve Care

Core Function	Ways Lab-Pharmacy Linkages Can Help
Drug Selection	1. Lab **Contraindicates** Drug
	2. Lab Suggests **Indication** for Drug
Dosing	3. Lab Affecting drug **Dose**
	4. Drug Requiring Lab for **Titration**
Monitoring	5. Abnormal Lab **Signaling Toxicity**
	6. Drug Warranting Lab **Monitoring** for **Toxicity**
Lab Interpretation	7. Drug **Influencing or Interfering** w/ Lab
	8. Drug **Impacting** on **Response** to Lab
Improvement	9. Drug Toxicity/Effects **Surveillance**
	10. Quality **Oversight**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PDR Labeled Lab-Pharmacy Warnings

Lab-Drug Category	Top 40 Drugs		New Drugs (N=37)	
Lab Result:	Total Warnings	# Drugs w/Warning	Total Warnings	# Drugs w/Warning
Contraindication for Drug	11	9	20	14
Indication for Drug	7	7	3	3
Dose Adjustment	40	31	28	23
Indicating Toxicity	169	39	161	32
Baseline Monitoring	16	11	12	8
Follow-up Monitoring	20	11	16	10
Interfered w/ by Drug	5	3	2	2
TOTAL	268	40	242	37

Drug-Lab Interactions in PDR FDA Legally Mandated Labeling

- 40 most commonly prescribed drugs 268 critical test & drug pairs
- 37 newest drugs on market
  242 critical test & drug pairs
- Average 6.6 drug-lab warning / drug

Schiff et al Arch Intern Med 2003

Adverse Drug Event Rates in Six Community Hospitals and the Potential Impact of Computerized Physician Order Entry for Prevention

Balthasar L. Hug, MD, MBA[1], Daniel J. Witkowski, MD, MS[2], Colin M. Sox, MD[3], Carol A. Keohane, BSN, RN[1], Diane L. Seger, RPh[1], Catherine Yoon, MS[1], Michael E. Matheny, MD, MSc[1,4], and David W. Bates, MD, MSc[1]

[1]Division of General Internal Medicine, Brigham and Women's Hospital, Boston, MA, USA; [2]Women's Healthcare Associates, P.C., Melrose, MA, USA; [3]Center for Child Health Care Studies, Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, Boston, MA, USA; [4]Decision Systems Group, Brigham and Women's Hospital, Boston, MA, USA.

CONTEXT: Medications represent a major cause of harm and are costly for hospitalized patients, but more is known about these issues in large academic hospitals than in smaller hospitals.

OBJECTIVE: To assess the incidence of adverse drug events (ADEs) in six community hospitals.

DESIGN: Multicenter, retrospective cohort study.

SETTING: Six Massachusetts community hospitals with 100 to 300 beds.

PATIENTS: From 109,641 adult patients hospitalized from January 2005 through August 2006, a random sample of 1,200 patients was drawn, 200 per site.

MAIN OUTCOME MEASURES: ADEs and preventable ADEs.

KEY WORDS: drug safety; adverse drug events; potential adverse drug event; computerized physician order entry; community hospital; Massachusetts.

J Gen Intern Med 25(1):31–8

DOI: 10.1007/s11606-009-1141-3

Medications represent a major cause of harm in hospitalized patients and were the single most frequent cause in the Harvard Medical Practice Study, accounting for 19.4% of injuries[1]. In another study carried out in two large academic hospitals, there were 6.5 adverse drug events (ADEs) per 100 admissions[2]. Of these ADEs, 28% were preventable, and 56% of preventable ADEs occurred during prescribing[3].

Computerized physician order entry (CPOE) systems have

- Recent community hospital ADE study
  - ADE rate -15/100 admissions
  - 49% serious
  - 11% life-threatening
  - 75% preventable

Hug. Adverse Drug Event Rates in Community Hospitals JGIM 2010

Table 7. ADE and Potential ADE Prevention Strategies

Prevention strategy	Preventable ADEs, all sites n (%)	Potential ADEs, all sites n (%)
Basic CPOE–legibility	-	19 (3.4)
Drug–laboratory check	37 (27.4)	26 (4.7)
Renal function check	26 (19.3)	74 (13.4)
Drug–dose suggestion	12 (8.9)	95 (17.2)
Drug cumulative dose check	-	106 (19.2)
Drug duration check	-	4 (0.7)
Drug–age check	12 (8.9)	4 (0.7)
Drug-specific guidelines	9 (6.7)	19 (3.4)
Drug–allergy check	5 (3.7)	12 (2.2)
Drug–frequency check	4 (3.0)	38 (6.9)
Drug–drug interaction check	3 (2.2)	17 (3.1)
Duplicate drug check	1 (0.7)	23 (4.2)
Patient characteristic[a]	1 (0.7)	9 (1.6)
Drug route suggestion	-	11 (2.0)
Not preventable by CPOE	25 (18.5)	95 (17.2)
Total	135 (100)	552 (100)

[a]*Patient continued to receive insulin while not receiving any food. CPOE = Computerized physician order entry*

Culture of Diagnosis Safety

JGIM
Journal of General Internal Medicine

JGIM
7/18

The Elusive and Illusive Quest for Diagnostic Safety Metrics

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J Gen Intern Med
DOI: 10.1007/s11606-018-4454-2

Not everything that counts can be counted, and not everything that can be counted counts.

Variously attributed to Albert Einstein, William Bruce Cameron, Lord Platt, and others[1]

Can't improve what you can't measure? Nonsense. Over the decades my relationship with my wife has continuously improved. But I've never administered a survey to her, nor tracked metrics of our relationship. Not only was this not needed for improvement, but likely would have been detrimental and disrespectful.

Don Berwick speaking at Institute for Healthcare Improve-

places to start. (Olson, Table 1). One clue that this may not be so simple is the fact that in their article, Olsen et al. mention twice that number of diagnoses as examples that would *not* lend themselves to the UDE measurement framework, including herpes zoster, pneumothorax, adult onset Stills, amyloid, Alzheimer's, depression, spinal metastasis, mitochondrial disorders, bacterial overgrowth, adrenal insufficiency, and certain psychiatric conditions.[6] Perhaps just by sheer coincidence, one of us (GS) has personally had two of these (zoster, pneumothorax) *misdiagnosed* by skilled physicians (in addition to initially self-misdiagnosing). Thus this list is revealing not only because it suggests several personally experienced diagnostic failures would be outside the purview of the UDE framework, but we suspect that applying their criteria strictly for the type "never-event" UDE's they advocate would exclude most of the diagnostic errors and problems in the diagnostic process that are occurring in healthcare today.

Let us examine just one of the diagnoses they suggest *would* be a good candidate, tuberculosis. TB is indeed important, being highly prevalent worldwide, as well as an important diagnosis not to miss or delay. Consider the consequences of

Culture of Diagnostic Safety & Improvement

1. **Driving out fear so no one afraid to ask questions, question a diagnosis, share when things go wrong**
   - Dealing w/ adverse events replacing blame & fear, w/ learning & improvement

2. **Organization-wide commitment to improving diagnosis, learning from diagnosis delays, diagnostic process errors**
   - Leadership/organizational recognition that misdiagnosis is the #1 top cause of patient-reported errors
   - Aggressive reporting, appreciative investigation, of adverse events
   - Relentless curiosity/worry/conferencing: what is wrong with patient; what might be missing, what can go wrong in system?
   - Obsession w/ details of dx process: what can go wrong, limitations of tests

Schiff JGIM 2018

Culture of Diagnostic Safety & Improvement

3. **Recognition uncertainty inherent in diagnoses, tests, illness presentation and evolution; anticipation of common pitfalls**
   - Situational awareness local, disease specific, literature reported vulnerabilities/pitfalls.
   - Reliable, proactive, follow-up safety nets & feedback systems to detect and protect
   - Conservative approaches to testing, imaging
     - Enabled by shared decision-making and reliable follow-up
4. **Respect human limitations, need for cognitive, process support**
   - Decreased reliance on human memory, minimizing negative effects of stress, fatigue, fear, recognizing limited ability to truly multitask.
   - Redesign EMRs & communication systems to support cognition, collaborative diagnosis, and follow-up
5. **Enhanced role for patient in co-producing diagnosis**
   - Working collaboratively to formulate history, diagnosis, monitor course, raise and research questions

DIAGNOSTIC ERROR IN MEDICINE 10TH INTERNATIONAL CONFERENCE

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Save the date for the **Diagnostic Error in Medicine 11th International Conference**, November 4-6, in New Orleans, LA. We hope to see you in 2018!

Supplemental Slides

Ten Principles for More Conservative, Care-full Diagnosis

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Abstract: Balancing tradeoffs between under-diagnosis (missing/delaying important diagnoses), and wasteful harmful over-diagnosis (labeling patients with "diseases" that may never cause suffering or death) represents an important current clinical and health policy issue. While often portrayed as the need to keep the pendulum from swinging too far in either direction, there is a need to view these two poles as two sides of the same coin, unified by the need for a more thoughtful, caring and conservative approaches to diagnosis.

We assembled an international panel of experts on diagnosis, primary care, patient safety, medical communication and quality improvement to create a framework for more conservative diagnostic practices to guide clinicians, policy makers, in promoting more appropriate and cost effective diagnostic approaches. Ten overarching principles emerged: the need to promote enhanced clinician modes of caring and listening, developing a new science of clinical uncertainty, rethinking ways symptoms are approached and diagnosed, maximizing continuity and trust to optimize knowledge of the patient and avoid financial conflicts, taming time to provide more time for clinical assessments and operationalize watchful waiting, more closely linking diagnosis to treatment options and decision-making, multifaceted efforts to educate and promote more appropriate test ordering based on awareness of testing harms and test limitations, incorporating lessons from the diagnostic errors safety movement to prioritize practices and provide patient safety nets, better addressing patient cancer fears and diagnosis challenges, and enhanced diagnostic stewardship roles for specialists and emergency department physicians.

Efforts to promote more judicious use of tests and referrals must be designed to improve care; they are ill-served if solely aimed at holding down costs and more likely to succeed if guided by these ten patient-centered principles.

For author affiliations, see end of text

Multiple, competing spotlights currently highlight the challenges associated with medical diagnosis. From one side, the recent National Academy of Medicine report suggests every person will experience at least one serious diagnostic error during their lifetime. Research has increasingly illuminated the problem of diagnostic errors and delays as the leading cause of medical malpractice claims (1-3). Uncertain and worried, patients and clinicians seek reassurance from diagnostic imaging, laboratory tests, and referral to specialists. On the other hand, clinicians and patients are being urged to use *fewer* diagnostic tests, and "Choosing Wisely" campaigns focusing on overuse of costly and/or potentially harmful diagnostic testing have been initiated in nearly every U.S. medical specialty and 20 countries worldwide (4-7). Evidence increasingly shows that reflexive ordering of tests and referrals or indiscriminate screening of asymptomatic patients often fails to provide definitive explanations or generate beneficial treatments and is often more harmful than beneficial (8).

Balancing tradeoffs between *under-diagnosis* (missing/delaying important diagnoses) and wasteful, harmful *over-diagnosis* (labeling patients with "diseases" that may never cause suffering or death) is often portrayed as the need "to keep the pendulum from swinging too far in either direction" (9). This framing of the problem as a simple tradeoff misses a fundamental dynamic. Instead of a one-dimensional continuum, we see the need for an approach that views under- and over-diagnosis as two sides of the same coin, unified by the need for a more thoughtful and caring approach (Table 1). This calls for a set of overarching principles to support improved clinician and patient decision-making and education, as well as guide health policy decisions to ultimately improve health outcomes and decrease costs.

Expanding from our previous work on principles of conservative medication prescribing (10, 11). We propose principles that apply the precautionary principle to diagnosis. The precautionary principle urges erring on the side of restraint in using new technology until we have sound evidence of benefit and long-term safety (12). We have combined this approach with core care, especially primary care, principles (care continuity, trusting relationships, good communication), and key patient safety lessons (situational awareness of pitfalls, safety nets to mitigate harm, culture to facilitate learning and avoid blame) (1, 13, 14). We assembled a diverse group of clinicians, educators, health policy and communication experts and developed the following 10 principles.

Table 1. Potential Labels for New Diagnosis Approach

What to Call This Approach to Diagnosis?
"More ... Diagnosis"

Conservative	Modest	Realistic
Judicious	Prudent	Honest
Mindful	Caring	Rational
Patient Centered	Appropriate	Safer
Shared	Cautious	Optimal
Listening	Skillful	
Relationship-based	Smarter	
Effective		

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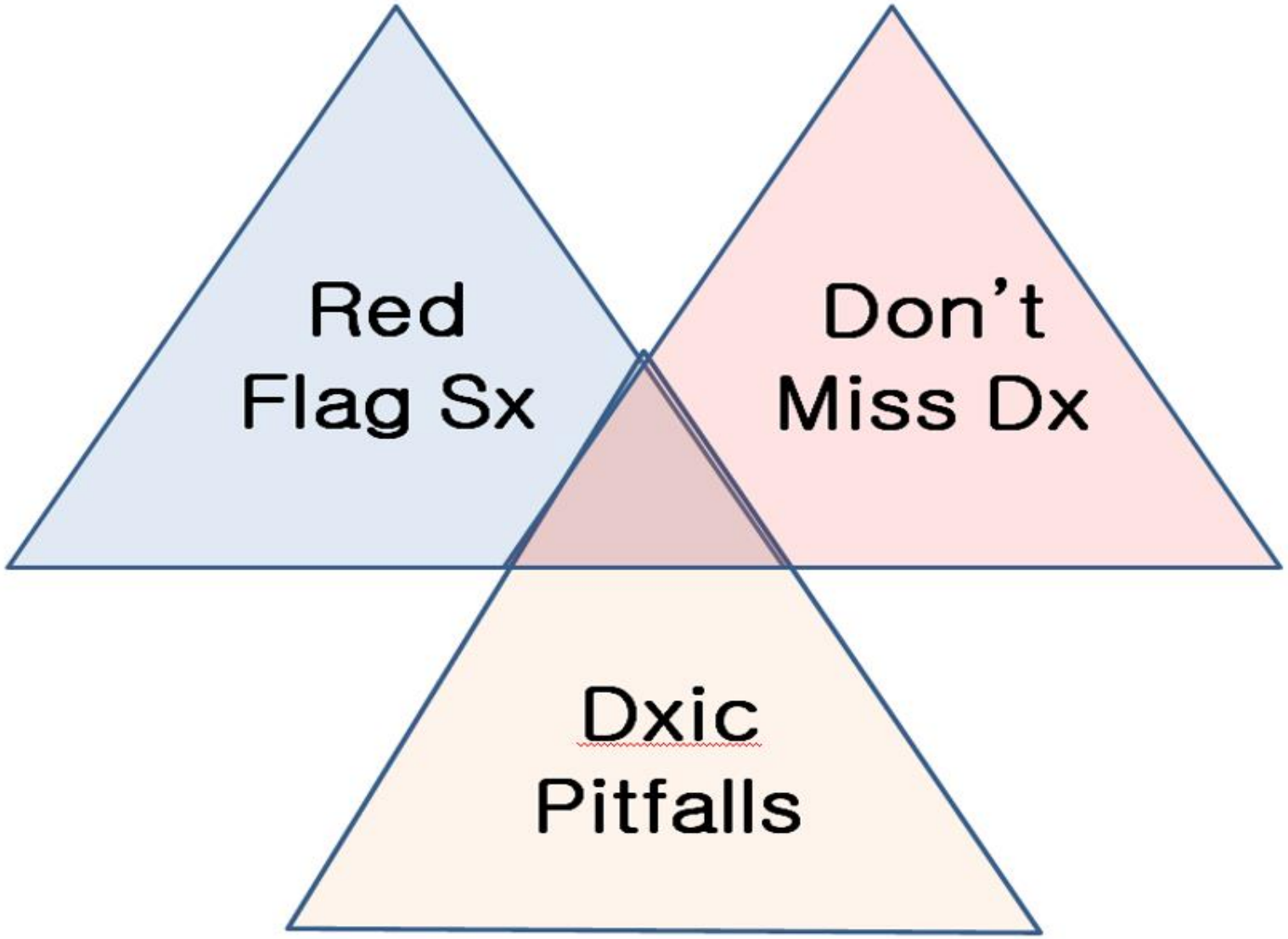
Diagnostic Situational Awareness Model



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OPEN ACCESS

Use of health information technology to reduce diagnostic errors

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ABSTRACT

Background Health information technology (HIT) systems have the potential to reduce delayed, missed or incorrect diagnoses. We describe and classify the current state of diagnostic HIT and identify future research directions.

Methods A multi-pronged literature search was conducted using PubMed, Web of Science, backwards and forwards reference searches and contributions from domain experts. We included HIT systems evaluated in clinical and experimental settings as well as previous reviews, and excluded radiology computer-aided diagnosis, monitor alerts and alarms, and studies focused on disease staging and prognosis. Articles were organised within a conceptual framework of the diagnostic process and areas requiring further investigation were identified.

Results HIT approaches, tools and algorithms were identified and organised into 10 categories related to those assisting: (1) information gathering; (2) information organisation and display; (3) differential diagnosis generation; (4) weighing of diagnoses; (5) generation of diagnostic plan; (6) access to diagnostic reference information; (7) facilitating follow-up; (8) screening for early detection in asymptomatic patients; (9) collaborative diagnosis; and (10) facilitating diagnostic feedback to clinicians. We found many studies characterising potential interventions, but relatively few evaluating the interventions in actual clinical settings and even fewer demonstrating clinical impact.

Conclusions Diagnostic HIT research is still in its early stages with few demonstrations of measurable clinical impact. Future efforts need to focus on: (1) improving methods and criteria for measurement of the diagnostic process using electronic data; (2) better usability and interfaces in electronic health records; (3) more meaningful incorporation of evidence-based diagnostic protocols within clinical workflows; and (4) systematic feedback of diagnostic performance.

INTRODUCTION

Unaided clinicians often make diagnostic errors. Vulnerable to fallible human memory, variable disease presentation, clinical processes plagued by communication lapses, and a series of well-documented 'heuristics', biases and disease-specific pitfalls, ensuring reliable and timely diagnosis represents a major challenge.[1–3] Health information technology (HIT) tools and systems have the potential to enable physicians to overcome—or at least minimise—these human limitations.

Despite substantial progress during the 1970s and 1980s in modelling and simulating the diagnostic process, the impact of these systems remains limited. A historic 1970 article[4] predicted that, by 2000, computer-aided diagnosis would have 'an entirely new role in medicine, acting as a powerful extension of the physician's intellect'.[5] Revisiting this prediction in 1987, the authors conceded that it was highly unlikely this goal would be achieved and that 'except in extremely narrow clinical domains (using computers for diagnosis) was of little or no practical value'.[5] In 1990 Miller and Masarie noted that a fundamental issue with many of these systems was that they were based on a 'Greek Oracle' paradigm whereby clinical information was provided to the computer with the expectation that it will somehow magically provide the diagnosis.[6] They suggested that a more useful approach would be to use computer systems as 'catalysts' to enable physicians to overcome hurdles in the diagnostic process rather than have the system become the diagnostician itself.

To understand and summarise how diagnostic accuracy can be enhanced, one needs a conceptual framework to organise HIT tools and their potential applications

Box 1 Condensed set of categories describing different steps in diagnosis targeted by diagnostic health information technology (HIT) tools

- Tools that assist in information gathering
- Cognition facilitation by enhanced organisation and display of information
- Aids to generation of a differential diagnosis
- Tools and calculators to assist in weighing diagnoses
- Support for intelligent selection of diagnostic tests/plan
- Enhanced access to diagnostic reference information and guidelines
- Tools to facilitate reliable follow-up, assessment of patient course and response
- Tools/alerts that support screening for early detection of disease in asymptomatic patients
- Tools that facilitate diagnostic collaboration, particularly with specialists
- Systems that facilitate feedback and insight into diagnostic performance

El-Kareh
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Suboptimization
How to recognize and avoid

- **Suboptimization refers to the process of optimizing one element of the system at the expense of the other parts of the system and the larger whole.**
  - Every lab perfecting own ordering, reporting system
  - Every unit in hospital its own system
  - Ditto every practice and doctor
- **Workarounds as both symptoms of and contributor to problems**

Tampering

- Reflex actions in response to errors
- Need to understanding/diagnose difference between special cause vs. common cause variation
- Responding to special cause as if it was common cause analogous to availability bias – where fail to weigh true incidence, instead overweigh more vividly recalled event.

Workarounds

- **Most diagnostic processes** developed in an ad hoc fashion over time; filled with workarounds and unnecessary steps and opportunities for error.
- **Workaround=bypass problems**
  - Often creative, innovative, successful
  - But temporary, suboptimal to fixing problem
  - Can mask embedded problems, inhibit solving
  - Worse yet, may introduce new problems

Redundancy

- Duplication of critical components of a system with the intention of increasing reliability of the system, usually in the case of a backup or fail-safe, or parallel systems
- However to extent redundancy increases complexity, dilutes responsibility and even encourages risk taking, should be questioned as safety strategy.
- Redundant systems can be costly, using valuable resources that could be freed for more reliable, productive system.

Role for Patient

In Minimizing and Preventing Diagnosis Error and Delay

- Push for timely access
- Reliable follow-up, continuity
- Keen observer, reporter sx
- Proactive on test results
- Sharing hunches
- Curiously reading on own
- Meticulously adhering w/ empiric trial regimens
- Active as co-investigator
- Co-grappling with Uncertainty
- Being patient: time & tests
- Recruiting family for support
- Respecting limits on staff time, society resources
- Agreeing to disagree
- Help in building, maintaining trust and communication
- Getting involved with patient organizations

Key question is:
What will it take at the provider and institutional end to support these roles and help them flourish?